GUIDANCE FOR DISPOSAL SITE RISK CHARACTERIZATION

AND RELATED PHASE II ACTIVITIES

- IN SUPPORT OF THE MASSACHUSETTS CONTINGENCY PLAN

MASSACHUSETTS DEPARTMENT OF ENVIRONMENTAL QUALITY

ENGINEERING

OFFICE OF RESEARCH AND STANDARDS

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FOREWORD

This document provides guidance for conducting Phase II risk characterizations per the Massachusetts Contingency Plan (MCP). The focus is primarily upon the public health risk characterization required in 310 CMR 40.545(3). Safety, public welfare and environmental risk characterizations required in 310 CMR 40.545(3)(h) are addressed briefly in this document.

The document is intended to be generally consistent with guidance provided in EPA's Superfund Public Health Evaluation Manual (October 1986), but includes additional guidance concerning specific requirements of M.G.L. Chapter 21E, the Massachusetts Oil and Hazardous Materials Release Prevention and Response Act, and the MCP. Utilization of this guidance will be helpful in providing consistent and conservative health risk characterizations at all Ch. 21E disposal sites in the Commonwealth.

This document should and will evolve with new risk assessment developments. Work continues which will address more issues in greater detail and which will incorporate recent innovations and changes in the risk assessment field. Users of this document are encouraged to submit comments on its content and format. Any recommendations for making the document more workable would be welcomed. Please submit them to:

Department of Environmental Quality Engineering
Office of Research and Standards
One Winter Street
Boston, MA 02108

(ATTN: Risk Assessment Section)

If you would like to be informed of any future revisions of this document, please send your name and address to the DEQE Office of Research and Standards (address above), ATTN: Guidance Document Mailing List. Periodic updates of individual sections or appendices may occur prior to the next formal revision of the entire document.

INTRODUCTION

This guidance document is intended for use by anyone conducting Phase II health risk characterizations for Chapter 21E disposal sites, as well as for the interested public. This document provides guidance for conducting health risk characterizations and related Phase II activities for disposal sites and for preparing the corresponding sections of the Phase II Report required in 310 CMR 40.545 of the Massachusetts Contingency Plan (MCP).

A Phase II Comprehensive Site Assessment involves a systematic investigation and assessment of an entire disposal site. The Phase II activities necessary to collect the required information and carry out this assessment are described in 310 CMR 40.545(3)(a) through (f). These activities include investigation of the physical characteristics of the site; identification of the source and extent of the release; characterization of the type, volume, nature, etc. of the released oil or hazardous materials (OHM); identification of exposure points and the concentration of OHM at these exposure points: and identification of background levels of OHM. Having collected the necessary Phase II information, risks of harm to public health must be characterized. As described in 310 CMR 40.545(3)(g) of the MCP, risks must be characterized by one of four methods. The Massachusetts Contingency Plan describes these four methods of public health risk characterization, and this document includes guidance for all four methods. Only one method should be used for a given disposal site. Guidance for selecting the appropriate risk assessment method is contained in SECTION I: Selection of Method for Conducting Risk Characterization. Correct choice of the appropriate method is extremely important.

The public health risk characterization methods and the particular sections of this document which apply to each type of characterization are described below and summarized in Table I. Please consult this table prior to commencing the risk characterization in order that all pertinent sections are completed.

Throughout this document, the risk characterization method described in 310 CMR 40.545(3)(g)1. will be called Method 1. This method applies to disposal sites at which standards exist for each OHM reported in each contaminated medium. The risk assessment method described in 310 CMR 40.545(3)(g)2. will be called Method 2. This method applies to disposal sites for which a promulgated set of clean-up levels has been determined to apply. The risk assessment method described in 310 CMR 40.545(3)(g)3.a. will be called Method 3.a., and the

method described in 310 CMR 40.545(3)(g)3.b. will be called Method 3.b. These methods apply to disposal sites at which there is neither a standard nor set of clean-up levels which can be applied to each OHM in all the contaminated media. Method 3.a. applies to "Single Medium" situations, and Method 3.b. applies to "Multi-Media" situations. Not all sections of the document apply to each method. Table I describes which particular sections of this document apply to each type of disposal site.

The major components of a health risk assessment include (1) Hazard Identification, (2) Dose Response Assessment, (3) Exposure Assessment, and (4) Risk Characterization. The guidance document has been arranged to address each of these components and serves as a model by which the requirements of the MCP may be satisfied. The guidance presented herein has been developed to encourage consistent evaluation of Chapter 21E disposal sites as well as to streamline the review process. The Department recognizes, however, that site specific conditions or alternative risk assessment techniques may result in a Phase II Report that differs in format from the guidance provided. Each Phase II Report will be reviewed by the Department to insure that all requirements of the MCP have been met. Those risk characterizations which differ substantially from the techniques presented in this guidance document may be subject to more lengthy Departmental review.

For each disposal site, regardless of the method of risk characterization used, hazards associated with oil and hazardous material located at the disposal site and the surrounding environment must be identified. Guidance provided in SECTION II - Hazard Identification pertains to the acquisition and reporting of data necessary to identify which OHM are present and to identify the toxic hazards associated with each OHM. Sampling plans are discussed. The sampling should not only identify hot spots or the source of OHM, but also produce data which can be used to assess exposures at the disposal site. Guidance is also given on the preparation of toxicity profiles for oil and hazardous materials present at a disposal site. These toxicity profiles will be used to provide information to communities in which disposal sites are located.

The dose-response assessment defines the relationship between the dose of oil or hazardous material received and the likelihood that various adverse health effect might occur. SECTION III - Dose-Response Assessment provides guidance for risk assessments conducted per Method 3.b. and assessments in which guidelines are developed per Method 3.a. In this section the relevant types of information for assessing both threshold and non-threshold effects are presented. Risk Characterizations performed according to Method 1 and Method 2 do not require a dose response assessment.

In order to adequately evaluate exposures at a disposal site it is necessary to identify potential human receptors, the pathways through which the OHM may migrate to reach these receptors, and the route of exposure that results in their actual exposure (i.e. ingestion, inhalation or dermal absorption). Guidance provided in SECTION IV - Exposure Assessment addresses these issues as well as the selection and application of analytical data necessary to estimate existing or potential exposures at or from a disposal site. This guidance applies to all disposal sites and all methods of risk assessment. Guidance is also provided on the relevant site-specific and chemical-specific parameters to consider when using models that estimate exposures. Equations for estimating doses are presented for use with disposal sites evaluated according to Methods 3.a. and 3.b.

The final step in the risk characterization process involves the estimation of risk and the determination of whether the disposal site presents risks to human health which require remediation. SECTION V - Risk Characterization describes the comparisons necessary to make this determination. For Method 1, exposure point concentrations must be compared to existing standards. For Method 2, exposure point concentrations must be compared to preexisting clean-up levels. For Method 3.a., exposure point concentrations must be compared to existing standards, guidelines and policies, or to a site-specific guideline developed and proposed in the Phase II Report. Finally, Method 3.b. requires the comparison of exposure point concentrations to existing standards, as well as the calculation of Total Site Risks. These Total Site Risks are then compared to the risk limits contained in the MCP.

The Massachusetts Contingency Plan requires that the risk of harm to health, safety, public welfare and the environment be characterized. The safety, public welfare and environmental risks should be evaluated according to the guidance given in Section VI. Though extensive guidance is not yet available in this area, SECTION VI - Safety, Public Welfare and Environmental Risk Characterization briefly describes the requirement to compare site conditions and conditions in the surrounding environment to safety, public welfare and environmental standards, guidelines and policies.

Finally, SECTION VII - Uncertainty Analysis briefly discusses the treatment of uncertainty in the risk characterization process, and SECTION VIII - Outline for Phase II Risk Characterization provides a suggested format for presentation of the risk characterization.

Additional guidance is provided in the Appendices. Appendix A presents a method for developing health/risk-based guidelines for use in Method 3.a. Appendix B presents suggested default assumptions which can be used to estimate average daily doses. Appendices C,D,and E list potentially applicable or suitably analogous standards, guidelines and policies. Appendix F contains a glossary of terms including key definitions which appear in the Massachusetts Contingency Plan. Appendix G contains suggested formats for the presentation of data and other health risk information in the Phase II Report. Appendix H contains worksheets and lists of parameters to be considered when developing guidelines for contaminants in ambient air. Air guidelines should be developed according to the process described in Chemical Health Effects Assessment Methodology and Method to Derive Ambient Air Limits (DEQE, 1989). Appendix I is reserved for future publication of sets of clean-up levels that would apply to certain disposal sites which occur frequently. Appendix J contains a list of Acceptable Threshold Concentrations (ATCs) to be used to calculate allowable inhalation doses for use in Hazard Index calculations and for back-calculation to allowable daily doses in the absence of Reference Doses. Finally, Appendix K contains a list of those components of the risk characterization report upon which will DEQE will focus its review.

The guidance presented in this document should also be used to demonstrate that a selected remedy (Phase III) eliminates significant risk of harm to health, safety, public welfare and the environment for any foreseeable period of time, and therefore meets the requirements in 310 CMR 40.545 (3)(i) of the MCP.

Public health considerations are just one component of the requirements for a temporary or permanent solution at a M.G.L. Chapter 21E disposal site. Risks to public safety, welfare and the environment must also be considered, as well as the feasibility of remediating to levels which would exist in the absence of the disposal site.

TABLE I - APPLICATIONS OF GUIDANCE DOCUMENT SECTIONS TO RISK ASSESSMENT METHODS

Section of MCP which guides evaluation of disposal site	Sections of Guidance Document Which Apply	
Method 1. 310 CMR 40.545(3)(g) 1.	Hazard Identification	SECTION II
	Exposure Assessment	SECTION IV A,B,C,D
	Standards	APPENDIX C
	Risk Characterizations	SECTION V A & SECTION VI
	Uncertainty Analysis	SECTION VII
	Suggested Outline	SECTION VIII
Method 2. 310 CMR 40.545(3)(g) 2.	Hazard Identification	SECTION II
	Exposure Assessment	SECTION IV A,B,C,D
	Sets of Clean-up Levels	APPENDIX I
	Risk Characterizations	SECTION V B & SECTION VI
	Uncertainty Analysis	SECTION VII
	Suggested Outline	SECTION VIII
Method 3.a. 310 CMR 40.545(3)(g)3.a.	Hazard Identification	SECTION II
	Dose-Response Assessment	SECTION III
	Exposure Assessment	SECTION IV A,B,C,D
	Standards	APPENDIX C
	Guidelines	APPENDIX D
	Policies	APPENDIX E
	Risk Characterizations	SECTION V C & SECTION VI
	Uncertainty Analysis	SECTION VII
	Suggested Outline	SECTION VIII
Method 3.b. 310 CMR 40.545(3)(g)3.b.	Hazard Identification	SECTION II
	Dose-Response Assessment	SECTION III
	Exposure Assessment	SECTION IV (ALL)
	Standards	APPENDIX C
	Risk Characterizations	SECTION V D & SECTION VI
	Uncertainty Analysis	SECTION VII
	Suggested Outline	SECTION VIII

N.B. - Exposure Assessment, SECTION IV A,B,C,D includes the identification/estimation of Exposure Point Concentrations (EPC), but does NOT include subsections E & F (Estimation of an Average Daily Dose and the Development of Exposure Profiles). ONLY Method 3.b. will use all parts of SECTION IV.

I. SELECTION OF METHOD FOR CONDUCTING HEALTH RISK CHARACTERIZATION

ONLY ONE METHOD WILL BE USED AT ANY GIVEN DISPOSAL SITE

The selection of a Method is based on information collected in Phase II activities up to and including 40.545 (3)(d). Once receptors, exposure points, and exposure routes are identified, and it is known which oil or hazardous materials (OHM) are or may be present at these exposure points, the method for risk assessment is selected as described below. Having selected a method, Table I should be consulted for the appropriate sections of this document which apply to that method.

N.B. - The Department will not approve a Phase II Risk Characterization Report in which an inappropriate Risk Characterization Method has been used.

* If upon consulting the "Standards" section of this guidance document (Appendix C), it is determined that applicable or suitably analogous standards (NOT guidelines, NOT policies) exist for all oil and hazardous materials in all exposure media at all exposure points, the disposal site will be evaluated per Method 1.

* If Method 1 is not appropriate, consult 310 CMR 40.800, which will contain specific sets of clean-up levels. (At the time of publication of this document, there are no such sets of clean-up levels.)

  If upon consulting the "Specific Sets of Clean-up Levels" (also contained in Appendix I of this Guidance Document), it is determined that a "Specific Set of Clean-up Levels" found in 310 CMR 40.800 is applicable to the disposal site, the disposal site may be evaluated per Method 2. A "Specific Set of Clean-up Levels" would be applicable to a disposal site if it addresses all OHM at all exposure points and is consistent with all current and reasonably foreseeable future uses of the disposal site and surrounding environment. At the Potentially Responsible Party's (PRP) option, the disposal site may alternatively be evaluated per Method 3.

If neither Method 1 nor 2 is appropriate, then a determination must be made whether the site fits the characteristics of a "Single Medium" disposal site, to be evaluated per Method 3.a. (310 CMR 40.545(3)(g)3.a.)

* If exposure to the oil or hazardous materials at or from the disposal site occurs via one contaminated medium, then Method 3.a. should be used. These situations are ones which would normally be addressed by a single medium-specific regulatory program (or Division) within the Department.

EXAMPLE: The DEQE Division of Air Quality Control (DAQC) historically regulates the discharge of chemicals to the ambient air. At a 21E disposal site, if no human exposures would be expected to occur other than via the air, the site would be considered "single medium". The risks associated with such a disposal site should be characterized in a manner consistent with Method 3.a. and the standards, guidelines and policies of the Division of Air Quality Control.

EXAMPLE: The DEQE Division of Water Supply (DWS) regulates contamination reported in sources of public drinking water supplies. At a 21E disposal site, if human exposure were to occur ONLY via contaminated drinking water, then the site would be considered "Single Medium". This is true, even though exposure is thought to occur via ingestion of the contaminated water, dermal contact with the contaminated water and via inhalation of volatilized contaminants from the drinking water supply. The risks associated with such a disposal site should be characterized in a manner consistent with Method 3.a. and the standards, guidelines and policies of the Division of Water Supply.

* If neither Method 1, 2 nor 3a is considered appropriate, then the risk characterization should be conducted according to Method 3.b. (310 CMR 40.545 (3)(g)3.b.). Method 3.b. should be considered only after Methods 1, 2 and 3.a. have been evaluated and determined to be inappropriate.

  If exposure to the oil or hazardous materials at or from the disposal site occurs via more than one contaminated medium ("Multi-Media Sites"), then Method 3.b. should be used.

EXAMPLE: Human exposure to oil and hazardous material at or from a disposal site is thought to occur as a result of contaminated soil at the site. The exposure pathways considered in the evaluation include ingestion of contaminated soil, dermal contact with the

contaminated soil, inhalation of OHM volatilized from the soil and inhalation of fugitive dust from the disposal site. Thus there is exposure to OHM in both the soil and air. At this time, no division of DEQE routinely regulates soil contamination. This disposal site would be characterized using Method 3.b.

EXAMPLE: A 21E disposal site has been reported with a plume of contaminated groundwater extending beyond the site boundaries. Volatilization of contaminants to the ambient air (to residential basements, for example) has been reported, resulting in human exposures via inhalation of that air. If the contaminated groundwater is used as drinking water then human exposure may also occur via ingestion, dermal and inhalation pathways related to the drinking water. This disposal site would be characterized using Method 3.b.

(Note: If the groundwater is not, and never will be used as a source of drinking water in this example, then exposure would only occur via inhalation of OHM volatilized from the groundwater to the ambient air. In that case, it would be considered a "single medium" site, evaluated by Method 3.a.)

II. HAZARD IDENTIFICATION

This section applies to all risk assessments conducted using Methods 1, 2, 3.a. and 3.b.

For each disposal site, hazards associated with OHM located at the disposal site and the surrounding environment must be identified. This guidance is limited to the identification of human health hazards at disposal sites as required in Phase II. At all such disposal sites, the Phase II Report required in 310 CMR 40.545 (4) shall contain summaries and raw data for chemical analysis results, presented by environmental medium. In addition, for all disposal sites, either a complete Toxicity Profile or a brief descriptive Toxicity Summary for each OHM evaluated shall be presented in the Phase II Report. The collection and presentation of this information should be conducted in a manner consistent with the following guidance.

A. IDENTIFICATION OF EXTENT OF RELEASE OF OHM

As required by 310 CMR 40.545(3)(b), the horizontal and vertical extent and concentrations of OHM at and from the disposal site in all media shall be established for each area of release of oil or hazardous material. The Phase II Report shall contain summary tables which clearly indicate which oil or hazardous materials at or from the disposal site have been identified in each medium at the disposal site and the surrounding environment. A separate table or set of tables shall be presented for each environmental medium. These tables shall also present the range of reported concentrations for each OHM detected at the disposal site and in the surrounding environment.

Though useful as an initial screening tool, measurements of Total Petroleum Hydrocarbons (TPH), Total Oil and Grease, Total Volatile Organic Compounds (Total VOCs) or Total Semi-Volatile Organic Compounds (Total SVOCs) are NOT adequate for characterizing exposures at a disposal site. There are currently no health-based standards or guidelines for these parameters which would allow for their use. In order to fully utilize the available compound-specific toxicologic information, analyses should be compound specific.

Particular attention should be given to the adequacy of site sampling. Often times site sampling does not produce the data necessary to characterize exposures at a disposal site. The sampling plan should insure the collection of data which can adequately characterize exposures and risks at the disposal site. Exposure

points and the activity patterns of potential receptors should be considered before the sampling is performed. A description or illustration of the sampling design (random, cluster, grid, stratified, etc.) should be included.

In addition to the raw data, the limit of detection (LOD) and practical quantitation limit (PQL) should be reported for each substance analyzed. The limit of detection is the smallest concentration or amount of a substance that can be reliably detected by a given measurement process and distinguished from background noise. The practical quantitation limit is the smallest concentration or amount of a substance for which quantitative results may be obtained with a specified degree of confidence. Typically the limit of detection represents the concentration at which the signal to noise ratio is three while the practical quantitation limit represents the concentration at which the signal to noise ratio is roughly thirty. If the laboratory uses a different interpretation scheme, that scheme should be reported.

Analytical results below the limit of detection are often reported as "not-detected" and results below the practical quantitation limit but above the limit of detection are often reported as "trace". Section IV.D.3. discusses how these values should be incorporated into the estimation of exposure point concentrations.

B. TOXICITY PROFILES

As part of the Hazard Identification component of the risk assessment, toxicity profiles shall be prepared or obtained and presented in the Phase II Report. Toxicity Profiles should be provided for all compounds of concern present at the disposal site and carried through the risk characterization process. (The use of "Indicator Compounds" used to represent a group of chemicals is generally NOT consistent with the MCP requirement that risk be evaluated for all OHM at or from the disposal site.) These profiles shall be summaries of the potential human health hazards posed by each OHM.

If there is a standard, guideline or clean-up level published by the DEQE in the Appendices of this document for the OHM of concern, a brief descriptive summary may replace the in-depth toxicity profile described below. This descriptive summary should include the known health effects associated with the OHM and the basis for the existing standard, guideline

or clean-up level. The purpose of the descriptive summary is primarily to inform and educate the public.

When no standard, guideline or clean-up level is published by the DEQE for a particular OHM, an in-depth profile is required to fully evaluate the toxicity of the substance.

The human health toxicity profiles should include comprehensive information on the topics listed in Figure 1. A suggested approach for developing a toxicity profile is to use the Chemical Health Effects Assessment Methodology (CHEM, DEQE 1989) to derive a weight of evidence classification and a hazard score for carcinogenicity, mutagenicity, developmental and reproductive toxicity, and acute/chronic toxicity. CHEM identifies reliable information sources and utilizes worksheets, examples of which are provided in Appendix H.

These profiles will be used to support any guidelines developed per Method 3.a. (310 CMR 40.545(3)(g)3.a.) or the estimation of Total Site Risks per Method 3.b. (310 CMR 40.545(3)(g)3.b.).

Figure 1

Human Health
Toxicity Profile Outline

I. Toxicokinetics

A. Absorption
1. Human
a. oral
b. dermal
c. inhalation
2. Animal
a. oral
b. dermal
c. inhalation

B. Distribution
1. Human
a. oral
b. dermal
c. inhalation
2. Animal
a. oral
b. dermal
c. inhalation

C. Metabolism
   1. Human
   2. Animal

D. Elimination
   1. Human
   2. Animal

II. Toxicity - Mechanism of Toxic Action Summary

A. Human
   1. oral
   2. dermal
   3. inhalation

B. Animal
   1. oral
   2. dermal
   3. inhalation

III. Mutagenicity

A. Data Summary

B. Classification - CHEM

IV. Acute Threshold Effects

A. Human
   1. oral
   2. dermal
   3. inhalation

B. Animal
   1. oral
   2. dermal
   3. inhalation

V. Chronic Threshold Effects

A. Human
   1. oral
   2. dermal
   3. inhalation

B. Animal
   1. oral
   2. dermal
   3. inhalation

C. Reference Dose

D. Hazard Score from CHEM (air only)

VI. Reproductive/Developmental Effects

A. Human
   1. oral
   2. dermal
   3. inhalation

B. Animal
   1. oral
   2. dermal
   3. inhalation

C. Classification - CHEM

VII. Carcinogenicity

A. Human
   1. oral
   2. dermal
   3. inhalation

B. Animal
   1. oral
   2. dermal
   3. inhalation

C. Classification - IRIS, CHEM

VIII. Structure Activity Relationships

IX. Interactions with other Substances

In the Phase II Report, references should be listed to document the sources of information provided in the toxicity profiles. Once the human health hazards have been identified, the dose-response relationships for those hazards shall be identified and presented in the Phase II Report, as descibed in Section III of this document. These dose-response relationships shall be used in the Risk Characterization activities for the disposal site.

III. DOSE-RESPONSE ASSESSMENT

This section applies only to risk characterizations conducted per Method 3.b. and to assessments in which guidelines are developed per Method 3.a.

The dose-response assessment describes the observed effects in humans and/or laboratory animals associated with particular doses of Oil or Hazardous Material (OHM). This information is obtained from published literature describing epidemiologic or toxicologic studies involving the particular OHM.

For each OHM reported at the disposal site, its dose-response relationship(s) must be described. The information on dose-response is later coupled with information on the nature and magnitude of the human exposure in order to characterize risk.

The dose-response information may be divided into two categories depending upon the nature of the human health endpoint:

- Information associated with threshold (non-carcinogenic) health effects.
- Information concerning carcinogenicity, either from human epidemiologic data or from laboratory studies.

A substance may be associated with both carcinogenic and non-carcinogenic health effects. Both must be evaluated. The classification of a chemical as a known or probable human carcinogen does not preclude an evaluation of that same chemical for potential non-carcinogenic health risks.

A. THRESHOLD EFFECTS

For non-carcinogenic health effects it is believed that a dose level exists at and below which no adverse health effects would be expected. Such a level is generally referred to as a threshold dose. While it is difficult to identify the theoretical threshold dose for a given chemical, it is possible to estimate a human sub-threshold dose at which no adverse health effects would be expected. Such a value is derived from the No Observable Adverse Effects Level (NOAEL) by application of uncertainty factors (UF) to account for interspecies variation and to protect sensitive populations. Important factors to consider when identifying and using such a sub-threshold dose include:

- the route of administration of the dose (inhalation, oral, dermal contact, etc...)
- the duration of exposure to that dose (lifetime, chronic, subchronic, or acute exposure)
- the absorption efficiency (if any) used to calculate that dose
- the age of the person receiving the dose.

Several types of "sub-threshold dose" values have been developed for use in risk assessments. The following section briefly describes several different values which could be used in this evaluation and are readily available. Note that the quality and quantity of information available for various chemicals will vary widely. When several toxicity values are available, it is important to choose among them. For the characterization of non-carcinogenic health risk (per Method 3.b.) and the development of health based guidelines (per Method 3.a.), the Department recommends the use of the US EPA derived Reference Dose (RfD). In the absence of an RfD (or when evaluating an exposure of less-than-lifetime duration), the alternative sources should be considered in the order presented below. As new values are constantly being proposed and old values are updated, it is important that each toxicity value be adequately referenced and that the most recent values be used.

When an RfD or an alternative toxicity value is not available or is considered inappropriate for use for a particular chemical, the risk assessor may develop and propose an acceptable human sub-threshold dose for use in the assessment. The review and approval by the Department of such a proposed alternative value would depend upon the justification and documentation provided to support it.

The Dose-Response Assessment should list the toxicity values identified for each OHM reported at the site.

1. <u>Reference Dose (RfD)</u>

The term "Reference Dose" applies only to US EPA verified values, and is expressed in units of mg/kg body weight/day. Current values of the RfD may be found in the EPA's Integrated Risk Information System (IRIS).

The Reference Dose is a benchmark human dose derived by the application of uncertainty factors (reflecting the quality of the data used to determine the RfD) to the available animal or human data and sometimes an additional modifying

factor based upon a professional judgement of the entire database of the chemical. A detailed description of the Reference Dose may be found in the IRIS Supportive Documentation, Volume 1, Appendix A.

The Reference Dose is based upon the assumption of a 70 year, lifetime exposure. The Reference Dose is not the highest dose expected to cause no adverse effect. It is an approximation of a dose at which no adverse health effects would be expected, with considerable conservatism built in.

The Reference Doses derived to date are for exposures via the oral route. It is expected that Inhalation RfDs will be available from the EPA in the future.

2. Allowable Doses Back-Calculated From The Allowable Threshold Concentration (ATC)

The Allowable Threshold Concentration (ATC) is a value derived from the Threshold Effects Exposure Limit (TEL) described in CHEM (DEQE, 1989). (The TEL value represents 20% of an allowable concentration, or ATC. Thus the ATC is equal to five times the TEL. The TEL was derived in a manner considering children to be the most sensitive potential receptors.) The ATC is a concentration of the OHM in air which would not be expected to result in adverse non-carcinogenic health effects. Appendix J lists the ATC value for 105 substances. The ATC is derived considering acute and chronic threshold health endpoints, including reproductive effects.

An acceptable daily dose used in the evaluation of inhalation exposures may be back-calculated from the Allowable Threshold Concentration. (See Appendix J).

3. Allowable Doses Back-Calculated From Drinking Water Standards and Guidelines

Drinking water standards and guidelines, which give the allowable concentration of a contaminant in drinking water supplies, include: the Maximum Contaminant Level (MCL), the Maximum Contaminant Level Goal (MCLG), and Health Advisories (HA). In general, an allowable daily intake comparable to the RfD may be obtained from the drinking water concentration by a series of back-calculations which reverse the process originally used to

derive the standard or guideline. Due to the varied methodologies used to develop these values (in luding the use of uncertainty factors, relative source of contribution, technical feasibility, etc...), it is vital that the risk assessor understand the basis of each value before an attempt is made to derive a sub-threshold dose via back-calculation!

Maximum Contaminant Level Goal (MCLG): The MCLGs (formerly the Recommended Maximum Contaminant Levels, or RMCLs), are health goals set by the EPA at levels which would result in no known or anticipated adverse health effects with a "margin of safety". MCLGs for substances considered to be carcinogenic are set at zero because the EPA assumes that any level of exposure is associated with some level of risk. MCLGs for substances not treated as known or probable human carcinogens are based upon chronic toxicity or other health data and applied uncertainty factors.

N.B. Back-calculation from the MCLG is only appropriate for use in the evaluation of compounds not considered Class A or B carcinogens.

Maximum Contaminant Level (MCL): The MCLs are enforceable standards and are set as close to the MCLGs as is feasible. This means that factors are considered which are not strictly health-based, such as treatment technology and cost. These factors must be assessed before an MCL is used to derive a sub-threshold dose.

N.B. For this reason, MCLs are not always considered appropriate values from which a chronic sub-threshold dose may be back-calculated.

Health Advisories (HA): Formerly called Suggested No Adverse Response Levels (SNARLs), Health Advisories describe concentrations of drinking water contaminants at which adverse non-carcinogenic health effects would not be expected to occur over specific exposure durations. Health Advisories are developed for 1-day, 10-day, longer-term (generally up to 2 years), and lifetime exposures based only on data describing non-carcinogenic endpoints of toxicity. For those substances which are known or probable human carcinogens, Health Advisories for lifetime exposure are not derived. The documentation for each HA should be consulted before proceeding with any calculations.

4. Allowable Doses Back-Calculated From Ambient Water Quality Criteria

Ambient Water Quality Criteria (AWQC) were developed by the US EPA Office of Water Regulations and Standards per Section 304 (a)(1) of the Clean Water Act of 1977. The AWQC consider both toxicity to aquatic life and human health effects. The AWQC do not consider technical feasibility or cost and may be used to derive a chronic sub-threshold dose for use in a risk assessment. However, it must be noted that the AWQC incorporate factors which account for exposure via both drinking water ingestion and consumption of contaminated fish. The documentation for each AWQC should be consulted before proceeding with any calculations.

5. Allowable Intake, Chronic (AIC) or Subchronic (AIS)

The Allowable Intakes, Chronic and Subchronic (AIC and AIS, respectively) are estimated sub-threshold doses, based upon exposure periods of a lifetime and less than a lifetime (respectively). An AIS (subchronic exposure) may be based upon 10 - 90 day animal studies.

Both the AIS and the AIC are in units of mg/kg body weight/day.

Allowable Intakes, Chronic and Subchronic, have been developed for both the oral and inhalation exposure pathways. The AIS or AIC (if available) may be found in the Health Effects Assessment document for each OHM, prepared by the Environmental Criteria and Assessment Office, US EPA, Cincinnati, Ohio, or in Appendix C of the Superfund Public Health Evaluation Manual, EPA 540/1-86/060 (US EPA 1986). These values should be used only when no other information is available.

N.B. - US EPA Reference Doses and other daily intakes which would not be expected to induce adverse threshold-type health effects (even if exposure were to continue for a lifetime) would be considered acceptable benchmarks for use in evaluating less-than-lifetime exposures to the same chemical. In other words, if an exposure is considered "acceptable" for a lifetime exposure then it is also "acceptable" for a fraction of that exposure.

The reverse, however, is not necessarily correct. Care must be taken to insure that the duration of exposure experienced by the theoretical receptor does not exceed the time period for which the toxicity value was developed. The RfD or other lifetime value may serve as a default benchmark.

EXAMPLE: A value derived from a 10-day Health Advisory is not an acceptable benchmark by which a 3-year exposure may be evaluated.

B. CARCINOGENIC EFFECTS

Unlike the non-carcinogenic health effects, it is generally assumed that there is no threshold dose for carcinogenicity, that there is no dose of a carcinogenic substance (other than no exposure) which is associated with zero risk. The Dose-Response Assessment should contain the following information for each chemical suspected to be a human carcinogen:

1. Classification

The EPA has developed a system for classifying chemicals according to the likelihood that the compound is a human carcinogen. The system is a modification of the International Agency for Research on Cancer (IARC) approach. It groups the chemicals into five classifications based upon the weight of evidence of the available data. (US EPA Guidelines for Carcinogen Risk Assessment, Federal Register/Vol. 51, No. 185/September 24, 1986).

GROUP A: CARCINOGENIC TO HUMANS

Sufficient evidence exists from epidemiological studies to support a causal association between exposure to the chemical and induction of cancer.

GROUP B: PROBABLE HUMAN CARCINOGEN

Group B_1 - Limited evidence exists from epidemiological studies indicating that the chemical is carcinogenic in humans.

Group B_2 - Sufficient evidence exists indicating that the chemical is carcinogenic in animals.

GROUP C: POSSIBLE HUMAN CARCINOGEN

Limited evidence exists indicating that the chemical is carcinogenic in animals.

GROUP D: NOT CLASSIFIED

The evidence indicating that the chemical is carcinogenic in animals is inadequate, or no data are available.

GROUP E: NO EVIDENCE OF CARCINOGENICITY TO HUMANS

There is no evidence that the chemical is carcinogenic in humans based upon at least two adequate animal studies in different species, or a combination of epidemiological and animal data.

The DEQE has developed an additional classification system which may be used in addition to the EPA classification to further describe the chemical. (Brown H.S., D.R. Bishop, and C.R. West, "A Methodology for Assessing Carcinogenic Hazards of Chemicals," Toxicology and Industrial Health, Vol. 2, No. 3, pp. 205-218; 1986)

2. Carcinogenic Potency Value

The Carcinogenic Potency (or Slope) Value for a chemical is derived by the EPA's Cancer Assessment Group (CAG). Using data derived from animal studies, the Potency Value is an estimate of the upper 95% Confidence Limit of the slope of the dose-response curve extrapolated to low doses. It is considered a measure of the cancer causing potential of a substance. For some chemicals, human epidemiologic data is the basis of an estimate of the carcinogenic potency. Current values for the Potency Value may be found in the EPA's Integrated Risk Information System (IRIS).

The Potency value is given in units of $(mg/kg/day)^{-1}$. It is based upon the concept of a lifetime average daily dose. Potency values have been derived for exposures via both the inhalation and oral routes.

3. Unit Risk Values

The Unit Risk is the incremental upper 95% Confidence Limit of the lifetime cancer risk estimated to result from lifetime exposure to an agent if it is in the air at a concentration of 1 ug/m^3 or in the drinking water at a concentration of 1 ug/L. These values (developed by the EPA's Carcinogen Assessment Group and available on IRIS) would be used in lieu of the chemical's Potency Value when an estimate of a lifetime average concentration of the chemical is available.

C. GROUPS OF CHEMICALS

There are several groups of closely related compounds for which the presentation and use of Dose-Response information has been problematic. These groups include: PAHs, Dioxins and PCBs. The evaluation of these compounds may be based upon: a.) the use of Toxic Equivalence Factors (TEFs, as for dioxins), b.) the use of dose-response information derived for a single compound as being representative of each member of that group (as Aroclor 1260 for PCBs) or c.) an alternative, documented methodology. Care must be taken, however, to insure that:

- ALL the compounds of the group reported at the site are included in the risk characterization
- Compounds reported to be carcinogenic are also evaluated for potential non-carcinogenic health effects.

D. SUMMARY OF DOSE-RESPONSE INFORMATION

The Dose-Response Data may be summarized in a Table(s) (See Appendix G) which should include:

- o The NAME and CAS NUMBER of each OHM reported at the site.
- o The DOSE-RESPONSE VALUE(S) (RfD, Equivalent levels derived from MCLG, HA, AWQC, etc..., AIC, AIS, ATC, TEF and/or Potency) associated with each OHM reported at the site.
- o The REFERENCE (including date) for each value reported.
- o The TARGET ORGAN(s) or HEALTH EFFECT(s) for which the RfD or equivalent value is derived.
- o The EPA CLASSIFICATION for each OHM considered carcinogenic.

IV. EXPOSURE ASSESSMENT

This section applies to all risk assessments conducted using Methods 1, 2, 3a and 3b. The Identification of Exposure Points and the Determination of the Exposure Point Concentrations required as part of the Phase II Activities (310 CMR 40.545 (3)(d)) should be carried out for each existing and reasonably foreseeable land use identified in 310 CMR 40.545 (3)(a) 9.

The exposure assessment is a critical component of the site assessment process. The exposure assessment must be consistent with the major question answered by the risk characterization process:

> If the disposal site is not remediated, based on the current and reasonably foreseeable use(s) of the disposal site and the surrounding environment, will OHM at or from the disposal site pose significant risk of harm to health, safety, public welfare or environment?

Therefore, the exposure assessment should incorporate conditions associated with both current use and reasonably foreseeable use in the absence of remediation. This is the nature of a BASELINE risk assessment.

Anticipated or proposed remedial actions should not be incorporated into the Phase II risk characterization. Generally, completed short-term measures or other completed non-permanent remedial actions should not be incorporated into the Phase II risk characterization. For example, temporary fencing of an area as a short term measure to eliminate direct contact with contaminated soils should not be incorporated into the Phase II process. Rather, the conditions which would exist in the absence of a temporary remedial or short-term measure should be evaluated. The Phase II exposure assessment should assume that no fence is in place.

There are, of course, exceptions to the general guidance. For example, if a completed short term measure permanently changes the exposure potential at a disposal site, such as the complete removal and disposal of contaminated soil, that short term measure would obviously be incorporated into the Phase II assessment.

> Proposed temporary or permanent solutions should be evaluated in Phase III. They should never be incorporated into the Phase II risk characterization.

To summarize, the Phase II exposure assessment should characterize the current and reasonably foreseeable exposures in the absence of remediation. In Phase III, it should be demonstrated that the selected remedy eliminates

any significant risk of harm to health, safety, public welfare and the environment. This demonstration may involve a risk characterization process which would then incorporate the proposed remedial measures.

A. IDENTIFICATION OF POTENTIAL HUMAN RECEPTORS

The information gathered during the Phase II investigation should be used to identify any existing or potential human receptors who are or who are likely to be exposed currently, or who it is reasonable to foresee are likely to be exposed in the future, to OHM at or from the disposal site. (310 CMR 40.545 (3)(d) 1.) Particular consideration should be given to sensitive subpopulations and to those with greater frequency of exposure.

Examples of potential human receptors may include, but should not be limited to:

Children who live and/or play at or near the disposal site.
Adults who live and/or work at or near the disposal site.
Adults and children who visit recreational areas at or near the disposal site.
Trespassers at the disposal site.

B. IDENTIFICATION OF EXPOSURE POINTS

For a potential Human or Environmental Receptor to be exposed to a contaminant at or from a disposal site, a realistic pathway must be established leading from the source of the OHM to the Receptor. Such a pathway would include a MIGRATION PATHWAY from the release source to a point of potential exposure. The Migration Pathway is comprised of three parts: 1) a Release Source (identified in 310 CMR 40.545 (3)(b)1), 2) a Release Mechanism, and 3) a Release (or Transport) Medium. All existing or potential migration pathways must be identified pursuant to 310 CMR 40.545 (3)(b) 4. Potential migration pathways may include transport or release via groundwater, surface water, air, soil or the food chain.

The potential points of exposure to be identified in 310 CMR 40.545 (3)(d) 2 may be at, near to, or distant from the disposal site. Exposure points describe an area of a disposal site or surrounding environment not necessarily a single, discrete point.

Typical Exposure Points and Migration Pathways include:

Exposure Point	Migration Pathway
Residential Neighborhood	Volatilization to Air
	Leaching into Groundwater
Playground	Release of Fugitive Dust to Air
	Tracking of Contaminated Soil
Adjacent Lake or Pond	Runoff to Surface Water

A summary table should include a list of the Exposure Points and the Migration Pathways which carry the OHM from the disposal site to the Exposure Point.

C. IDENTIFICATION OF EXPOSURE ROUTES

At the Exposure Point, the mechanism by which a Human Receptor receives a dose of OHM is called the EXPOSURE ROUTE. The Exposure Route describes the uptake of the contaminant from the migration medium by the receptor. Each Human Receptor may experience exposures via one or more Exposure Routes at an Exposure Point. Typical Exposure Routes would include:

INGESTION of contaminated soil, water or food
INHALATION of contaminated air or fugitive dust
DERMAL ABSORPTION from contaminated water, soil or sediments

All Exposure Routes must be identified for each Receptor of concern at each Exposure Point, pursuant to 310 CMR 40.545 (3)(d) 3.

D. IDENTIFICATION/ESTIMATION OF EXPOSURE POINT CONCENTRATIONS

This section addresses the issues involved in identifying and estimating exposure point concentrations. First, the regulatory distinctions between on-site and off-site exposure point concentrations are presented. Next, guidance is given on how to estimate exposure point concentrations that are representative of disposal site conditions. The selection of analytical data that are representative of exposures and the manner in which these data, including non-detects and trace values, are incorporated into the calculation of average exposure point concentrations are discussed.

Though direct measurement of exposure point concentrations is preferred, estimation of exposure point concentrations may be acceptable. Measured concentrations may serve as input to models which predict emissions, fate, transport or persistence. Modeling methods should be fully referenced and described. Some general guidelines and references for estimating exposure point concentrations are presented.

1. On-site vs Off-site Exposure Point Concentrations

As required by 310 CMR 40.545(3)(d), exposures to oil or hazardous materials at or from the disposal site must be identified and quantified.

For exposure points located at the disposal site, representative concentrations should be measured or estimated (modeled) ambient concentrations (background concentrations plus concentrations contributed by the disposal site) at a given point in time. Note that if the levels of OHM which would exist in the absence of the disposal site ("background") would prevent the achievement of the risk characterization criteria, then the Department may determine that such levels would meet the requirements of a permanent solution (as described in 310 CMR 40.545(3)(j)2.).

Exposures to OHM at or from the disposal site occur both on-site and off-site. Exposures to OHM from the disposal site at a location off-site should be evaluated exclusive of any contamination not originating at the disposal site. In other words, background concentrations should not be included in the estimation of off-site Exposure Point Concentrations. For exposure points located beyond the boundaries of the disposal site, representative concentrations should be the measured or modeled site contribution to ambient concentrations at that location at a given point in time. Appropriate points in time are to be identified with respect to dose-response functions and the environmental fate characteristics of the OHM being evaluated.

2. Selection of Analytical Data for Estimation of Exposure Point Concentrations

Analytical data will be generated during the Phase II Full Investigation in order to characterize the nature, concentration, and horizontal and vertical distribution of the oil and hazardous materials at

the disposal site. A sampling plan should be developed and followed to generate these data.

Analytical data for samples which are representative of actual or potential exposures should be selected for use in estimating representative exposure point concentrations. A representative exposure point concentration is used to calculate the average daily dose. If exposures are confined to a particular portion of the site only data taken from these areas should be included in the estimation of representative exposure point concentrations. If exposures predominate in one area, data from these areas should be weighted and incorporated into the calculation of exposure point concentrations accordingly. In addition, samples taken in inaccessible locations should not be considered when evaluating exposures via ingestion or dermal contact with surface soils. For example, use of data from samples taken under buildings or at a depth of ten feet may be appropriate only when there is a foreseeable mechanism for bringing humans into contact with the soil contaminants (e.g. excavation during construction, or a seasonal high water table which brings subsurface contaminants to the surface).

3. Treatment of Non-detects and Trace Values in the Estimation of Exposure Point Concentrations

In estimating exposure point concentrations, "trace" values and "non-detects" should be treated as follows. When the laboratory reports the concentration of an OHM in a sample as "trace", the concentration of the OHM in that sample should be assumed to be one-half of the Practical Quantitation Limit (PQL) (or the Method Detection Limit, MDL). When the laboratory reports the concentration of an OHM in a sample as "not detected" (i.e. below the Limit Of Detection, or LOD), the concentration of that OHM in that sample should be assumed to be zero. There may be exceptions to this guidance if detection limits are unusually high.

4. Calculating Exposure Point Concentrations

The exposure point concentrations should be calculated in a way that is consistent with the standard of comparison. Attention should be given to whether the standards or guidelines to which exposure point concentrations are being compared

represent averages over time. In addition, the frequency and distribution of both sampling data and exposures should be considered; sampling data should be appropriately weighted to represent actual exposures. In some cases involving chronic or subchronic exposures, it may be appropriate to consider the exposure point concentration to be the average of all data during a sampling event. In cases involving acute exposures, a maximum concentration may be more appropriate. Guidance is provided below for a variety of situations likely to be encountered.

a. Comparisons to Standards or Guidelines.

If comparing exposure point concentrations to standards or guidelines, the exposure point concentration may actually represent an average over time, e.g. the arithmetic mean of four quarterly samples for Maximum Contaminant Levels (MCLs), or annual average concentrations for Allowable Ambient Levels (AALs) in air. If using exposure point concentrations to calculate an average daily dose (ADD) or lifetime average daily dose (LADD) the exposure point concentration would generally represent a concentration at a single point in time. However, a lifetime average concentration might on occasion be used as an exposure point concentration.

b. Evaluation of Chronic or Subchronic Exposures.

In general, for chronic or subchronic exposure evaluations the weighted arithmetic or geometric mean of appropriate data points would be used as the concentration representative of exposures in a given area. Arithmetic means are typically used to represent data which are normally distributed while geometric means are typically used to represent data which are lognormally distributed. Because sampling data and exposures are not necessarily distributed uniformly across the site, consideration should be given to actual or potential exposure patterns as well as the sampling frequency across the site. At any given site, the following scenarios are possible:

i. frequency of sampling data may be unequally distributed across the site;
ii. frequency of exposure may be unequally distributed across the site;
iii. both frequency of sampling data and frequency of exposures may be unequally distributed across the site (these distributions may or may not be coincident);
iv. both frequency of sampling data and frequency of exposures may be equally distributed across the site (these distributions may or may not be coincident).

The calculation of representative exposure point concentrations should take these exposure patterns and sampling frequencies into account. At least two methods may be used to account for unequal exposures or unequal sampling frequency. The first method involves estimating a weighted average exposure point concentration that can then be used to calculate average daily dose. A weighted average exposure point concentration is considered a representative estimation of exposures at a given site. In this method, analytical data should be weighted in a manner which reflects the exposure patterns and the sampling frequency in the areas of actual or potential exposures.

EXAMPLE: If 20 equidistant samples were taken in a portion of a site approximately 50 meters by 50 meters, each sample can be said to represent 125 m^2 (2500 m^2 / 20 samples). If three additional equidistant samples were obtained from another portion of the site approximately 100 meters by 100 meters (in order to verify the assumption that the area was free of contamination) each sample could be said to represent 3333 m^2. If exposures are equally likely throughout the entire site, the sample values should be weighted according to the relative area each represents. If exposures are not equally likely throughout the site, sample values should be weighted according to both the relative area each sample value represents as well as the relative exposure likelihood in each area. Only data which represent actual or potential areas of exposure should be incorporated. The weighted average exposure point concentrations obtained from this exercise would be used as inputs to any

emission models, transport models, or persistence models which require an average concentration for OHM present at the site.

The second method involves calculating separate average daily doses for each subarea of exposure and then weighting the separate doses to estimate a total average daily dose which reflects exposure patterns at the entire site.

EXAMPLE: At a given site, 90 percent of the exposure time takes place on half of the site and 10 percent of the exposure time takes place on the other half of the site. The average exposure point concentration for the first half of the site should be calculated (sample frequency should be considered when calculating this average value). The average exposure point concentration for the remaining half of the site, upon which only 10 percent of total exposure time takes place, should also be calculated. Total average daily dose for the entire site would weigh the separate daily doses from each area according to the relative time of exposure in each area.

c. Evaluation of Acute Exposures.

In the case when short term exposures may result in adverse health effects, it may be important to consider the highest concentrations to which an individual may be exposed during this short period of time. In the case of acute exposure evaluations, a maximum reported value, or the geometric or arithmetic mean of data points in a small area may be chosen to represent the exposure point concentration.

5. Modeling of Exposure Point Concentrations

Though direct measurement of contaminants is preferred, there are times when it is necessary to estimate exposure point concentrations through the use of mathematical models. Exposures may be expected via air, groundwater, surface water, fish or soil, though analytical data may not be available for each relevant medium. Mathematical models can be used to estimate emissions, fate and transport, or persistence of contaminants in the environment and to estimate the concentrations of OHM at exposure points when measured data are not

available. Mathematical models refer to analytical solutions that can be performed using a hand calculator, or analytical or numerical models implemented as programs to be run on a computer.

In the absence of measured data, the need for mathematical modeling should be based on an assessment of the potential mobility of the contaminant from the location in which it was originally discovered to locations where exposure is likely to occur. For example, if contamination was originally discovered in soil, important questions to consider include the following:

- Is leaching of OHM possible?
- Is vapor release to air possible?
- Is release to groundwater or surface water possible?
- Is fugitive dust release to air possible?
- Is volatilization release to air possible?

Models that predict either intramedia or intermedia transport should consider site-specific as well as chemical-specific parameters. Potentially relevant site specific parameters include meteorological data, soil type, bulk density and porosity, stream velocity, and hydraulic conductivity. Potentially relevant chemical specific parameters include the appropriate phase transfer coefficients, Henry's Law Constant, vapor pressure and solubility.

Models must also be able to simulate the relevant physical processes occurring within the specified environmental setting. These processes may include adsorption, attenuation, diffusion, dispersion, volatilization, erosion or density effects related to temperature and concentration.

The data selected as inputs to mathematical models should be selected carefully and should be representative of the actual area where emissions contributing to exposures are occurring. If an average contaminant concentration is required as input to the model, the concentration would generally be the weighted arithmetic or geometric mean of all data for the medium of concern in the appropriate area during a sampling event.

When exposure point concentrations (EPC) <u>on-site</u> are being estimated via modeling techniques, the EPC will be the sum of the background concentration and the estimated incremental concentration contributed by the OHM from the

disposal site. When exposure point concentrations off-site are being estimated via modeling techniques, the EPC will be the estimated incremental concentrations contributed by OHM from the disposal site.

Techniques for modeling emissions, persistence and transport of OHM should be generally accepted and well documented. If models are commercially available, complete references including a brief discussion of the models input coefficients, assumptions and uncertainties should be provided. If models are not commercially available, source codes or other documentation which allows technical review of the model and a more complete discussion of the models input coefficients, assumptions and uncertainties should be provided. The following references may be helpful in selecting and evaluating the appropriateness of particular models:

Superfund Exposure Assessment Manual, (April 1988), EPA 540/1-88/001

Selection Criteria for Mathematical Models Used in Exposure Assessments - Surface Water Models, (July 1987), EPA 600/8-87/042

Selection Criteria for Mathematical Models Used in Exposure Assessments - Groundwater Models, (May 1988), EPA 600/8-88/075

Hazardous Waste Treatment, Storage and Disposal Facilities (TSDF) - Air Emissions Models. (December 1987), Office of Air Quality Planning and Standards. EPA-450/3-87-026.

E. ESTIMATION OF AVERAGE DAILY DOSE (ADD)

This section applies to risk assessments conducted per Method 3.b. and to risk assessments in which guidelines are developed per Method 3.a.

These operations should be used in calculating doses for the estimation of total site risks (Method 3.b.). These expressions for daily dose should also be used to calculate guidelines for Method 3a. as described in Appendix A. [However, if the risk estimate or proposed guideline is based upon a chemical's Unit Risk (See Section III.B.3.- Unit Risk) and a lifetime average concentration then a Lifetime Average Daily Dose would not be calculated.]

The US EPA Exposure Assessment Group defines exposure as the amount of material contacted and available for absorption. The dose is defined as the amount of material actually absorbed into the body. The application of a Bioavailability Adjustment Factor (BAF) or a "Relative Absorption Factor" (an EPA Region I term) is generally assumed to convert an exposure to a dose, although the actual role of such a factor is discussed in detail in Appendix B, Section K of this document. Each equation given in the following pages includes a Bioavailability Adjustment Factor, and, under certain situations, the result will in fact be an average daily exposure rather than a dose. For simplicity, we have retained the term "average daily dose" to apply to the product of an "average daily exposure" and a Bioavailability Adjustment Factor.

The equations presented below outline the procedure for the calculation of an Average Daily Dose of an OHM. Depending upon the period of time over which the total intake of contaminant is averaged (Averaging Period, or AP), the calculations may yield:

- Lifetime Average Daily Dose (LADD): The averaging period for a LADD is 70 years. A LADD should be calculated in order to estimate carcinogenic risk. (The exception being the use of Unit Risk, as noted above.) The actual exposure period could range from a day to an entire lifetime.

- Average Daily Dose, Chronic (ADD_C): The averaging period for an ADD_C may range approximately from several months duration to somewhat less-than-lifetime. The chronic daily dose is used to evaluate non-carcinogenic health effects associated with long-term exposure.

- Average Daily Dose, Subchronic (ADD_s): The averaging period for an ADD_s may range approximately from a few days to several months.. The subchronic daily dose is used to evaluate non-carcinogenic health effects associated with short-term or seasonal exposures.

- Average Daily Dose, Acute (ADD_a): The averaging period for an ADD_a is generally one day or less. The acute dose is used to evaluate non-carcinogenic health effects associated with onetime or episodic exposures.

The Averaging Period (AP) used in the following equations may not always be equal to the Duration of the Exposure Period (D_2).

Example: The risk assessor is asked to evaluate the carcinogenic risk associated with a five year exposure to chemical A. Estimation of carcinogenic risk requires the calculation of a Lifetime Average Daily Dose. Thus, the Averaging Period used for calculating the LADD would be 70 years while the Duration of the Exposure Period would be equal to 5 years.

The risk assessor is also asked to evaluate the likelihood of non-carcinogenic health effects associated with a five year exposure to chemical A. The assessor may calculate an Average Daily Dose Chronic (ADD_c) where AP = 5 yrs and D_2 = 5 yrs.

Frequently, it will be necessary to calculate several different daily doses of a chemical to a receptor in order to evaluate all the exposures scenarios which have been identified as being of concern.

The general form of the ADD equation is presented as:

$$ADD = \frac{(\text{Total Amount of OHM Taken In})}{(\text{Body Weight}_{avg})(\text{Averaging Period})}$$

The doses of an OHM received via different routes of exposure are assumed to be additive unless there is evidence otherwise.

General equations for the calculation of Average Daily Dose are presented in this section for some frequently encountered exposure pathways. These equations are not intended to represent the universe of potential models and they must be tailored to site-specific conditions. It is expected that additional exposure pathways may be identified, and an ADD may be calculated, using appropriate models, for each receptor of concern.

The Daily Dose(s) of each OHM calculated for each potential receptor may be summarized in the Phase II Report. In addition, summary tables presenting the equations and the exposure assumptions used to calculate the daily dose should be presented and well referenced. (See Appendix G)

1. Air

The equations which follow represent estimations of the actual dose of OHM received at an exposure point. The equation for calculating the dose associated with the Allowable Threshold Concentration (ATC) may be found in Appendix J.

a. Inhalation of OHM Contaminated Particulates

Airborne particulates (fugitive dust) may carry OHM to receptors both on- and off-site. An Average Daily Dose due to the inhalation of OHM contaminated particulates (ADD_{inhp}) may be calculated:

$$ADD_{inhp} = \frac{[RP]_{air} * [OHM]_{part} * VR * BAF * D_1 * D_2 * F * C}{BW_{avg} * AP}$$

Where:

$[RP]_{air}$ = Representative concentration of respirable particulates (PM_{10}) in the air at the Exposure Point during the exposure event. (dimensions: mass/volume)

$[OHM]_{part}$ = Representative concentration of OHM in the respirable particulates at the Exposure Point during the period of exposure. (dimensions: mass/mass)

VR = Daily respiratory volume for the receptor of concern during the period of exposure. (dimensions: volume/time)

BAF = Bioavailability Adjustment Factor

F = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)

D_1 = Average duration of each exposure event (dimensions: time/event)

D_2 = Duration of the exposure period (dimension: time)

BW_{avg} = Average body weight of the receptor of concern during the averaging period (dimension mass)

AP = Averaging Perio (dimension: time)

C = Appropriate units conversion factor(s)

b. Inhalation of Gaseous OHM

Gaseous Oil or Hazardous Material (for example, OHM volatilized from contaminated soil) may be inhaled both on- and off-site. An Average Daily Dose due to the inhalation of gaseous OHM (ADD_{inhg}) may be calculated:

$$ADD_{inhg} = \frac{[OHM]_{air} * VR * BAF * D_1 * D_2 * F * C}{BW_{avg} * AP}$$

Where:

$[OHM]_{air}$ = Representative concentration of gaseous OHM in the air at the Exposure Point during the period of exposure (dimensions: mass/volume)

VR = Daily respiratory volume for the receptor of concern during the period of exposure. (dimensions: volume/time)

BAF = Bioavailability Adjustment Factor

F = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)

D_1 = Average duration of each exposure event (dimensions: time/event)

D_2 = Duration of the exposure period (dimension: time)

BW_{avg} = Average body weight of the receptor of concern during the averaging period (dimension: mass)

AP = Averaging Period (dimension: time)

C = Appropriate units conversion factor(s)

2. Soil

The Average Daily Dose received by a receptor via direct contact with soil containing OHM (ADD_{soil}) is the sum of the ADDs for both absorption via dermal contact with the contaminated soil and ingestion of that soil.

$$ADD_{soil} = ADD_{dermal\ absorption} + ADD_{ingestion}$$

a. Dermal Contact with Contaminated Soil

The Average Daily Dose due to dermal contact with OHM contaminated soil (ADD_{sod}) may be calculated:

$$ADD_{sod} = \frac{[OHM]_{so} * SA * MS * BAF * F * D_1 * D_2 * C}{BW_{avg} * AP}$$

Where:

$[OHM]_{so}$ - Representative concentration of OHM in the soil at the exposure point during the period of exposure (dimensions: mass/mass)
SA - Skin surface area in contact with the soil on days exposed (dimensions: area/time)
MS - Mass of soil in contact with the unit surface area of skin (dimensions: mass/area)
BAF - Bioavailability Adjustment Factor (unitless)
F - Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)
D_1 - Average duration of each exposure event (dimensions: time/event)
D_2 - Duration of the exposure period (dimension: time)
BW_{avg} - Average body weight of the receptor of concern during the averaging period (dimension: mass)
AP - Averaging Period (dimension: time)
C - Appropriate units conversion factor(s)

b. Incidental Ingestion of Contaminated Soil

The Average Daily Dose due to the incidental ingestion of OHM contaminated soil (ADD_{soi}) may be calculated:

$$ADD_{soi} = \frac{[OHM]_{so} * I * BAF * F * D_1 * D_2 * C}{BW_{avg} * AP}$$

Where:

$[OHM]_{so}$ - Representative concentration of OHM in the soil at the exposure point during the period of exposure (dimensions: mass/mass)
I - Daily soil ingestion rate on days exposed during the exposure period (dimensions: mass/time)
BAF - Bioavailability Adjustment Factor
F - Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)
D_1 - Average duration of each exposure event (dimensions: time/event)
D_2 - Duration of the exposure period (dimension: time)
BW_{avg} - Average body weight of the receptor of concern during the averaging period (dimension: mass)
AP - Averaging Period (dimension: time)
C - Appropriate units conversion factor(s)

3. Sediment

The Average Daily Dose received by a receptor via direct contact with OHM contaminated sediment will be estimated in a manner similar to the calculation of the ADD for soil exposure, including both dermal contact with the sediment and incidental ingestion of that sediment.

4. Drinking Water

The Average Daily Dose received by a receptor via a source of drinking water is the sum of the ADDs for ingestion of the drinking water (ADD_{dwi}), dermal contact with the water (ADD_{dwd}), and inhalation of volatilized OHM from that water (ADD_{dwih}).

$$ADD_{dw} = ADD_{dwi} + ADD_{dwd} + ADD_{dwih}$$

a. Ingestion of Contaminated Drinking Water

The Average Daily Dose due to the ingestion of OHM contaminated drinking water (ADD_{dwi}) may be calculated:

$$ADD_{dwi} = \frac{[OHM]_{dw} * VI * BAF * D_2 * C}{BW_{avg} * AP}$$

Where:

$[OHM]_{dw}$ - Representative concentration of OHM in the drinking water at the exposure point during the exposure period (dimensions: mass/volume)
VI - Daily volume of drinking water ingested by the receptor of concern at the exposure point during the exposure period (dimensions: volume/time)
BAF - Bioavailability Adjustment Factor
D_2 - Duration of the exposure period (dimension: time)
BW_{avg} - Average body weight of the receptor of concern during the averaging period (dimension: mass)
AP - Averaging Period (dimension: time)
C - Appropriate units conversion factor(s)

b. Dermal Absorption of OHM Via Drinking Water

Dermal absorption and inhalation of OHM may occur while the receptor of concern is in contact with the drinking water. Typically these exposures would include showering, bathing, washing dishes, cooking and other household activities.

The Average Daily Dose received via dermal absorption from drinking water during household activities (ADD_{dwd}) may be calculated using the equation presented for Dermal Contact with Contaminated Surface Water (Section IV.E.5.b.). If information sufficient for calculating ADD_{dwd} is not available, default exposure assumptions in Appendix B. may be used.

c. Inhalation of OHM Volatilized from Drinking Water

The Average Daily Dose received via inhalation of OHM volatilized from drinking water (ADD_{dwih}) may be calculated using the equation presented for the Inhalation of Gaseous OHM in air (Section IV.E.1.b.).

If information sufficient for calculating ADD_{dwih} is not available, default exposure assumptions in Appendix B. may be used.

5. Surface Water

The Average Daily Dose received by a receptor via contaminated surface water (ADD_{sw}) is the sum of the ADDs for exposures resulting from dermal contact with the contaminated surface water (ADD_{swd}), incidental ingestion of the surface water (ADD_{swi}), and inhalation of gaseous OHM volatilized from the surface water (ADD_{swih}).

$$ADD_{sw} = ADD_{swd} + ADD_{swi} + ADD_{swih}$$

a. Dermal Contact With Contaminated Surface Water

The Average Daily Dose received via dermal absorption with contaminated surface water (ADD_{swd}) may be calculated:

$$ADD_{swd} = \frac{[OHM]_{sw} * SA * PC * BAF * F * D_1 * D_2 * C}{BW_{avg} * AP}$$

Where:

$[OHM]_{sw}$ - Representative concentration of OHM in the surface water at the Exposure Point during the period of exposure (dimensions: mass/volume)
SA - Skin surface area in contact with the surface water during the period of exposure. (dimension: area)
PC - Permeability Constant (dimensions: volume/time*area)
BAF - Bioavailability Adjustment Factor
F - Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)
D_1 - Average duration of each exposure event (dimensions: time/event)
D_2 - Duration of the exposure period (dimension: time)
BW_{avg} - Average body weight of the receptor of concern during the averaging period (dimension: mass)
AP - Averaging Period (dimension: time)
C - Appropriate units conversion factor(s)

b. Inhalation of OHM Volatilized from Surface Water

The Average Daily Dose received via inhalation of gaseous OHM volatilized from contaminated surface water (ADD_{swih}) may be calculated using the equation presented for the inhalation of gaseous OHM in air (Section IV.E.1.b.).

c. Incidental Ingestion of Contaminated Surface Water

The Average Daily Dose received via the incidental ingestion of contaminated surface water (ADD_{swi}) may be calculated using the equation presented for the ingestion of contaminated drinking water (Section IV.E.4.a.).

6. Food

The Average Daily Dose received via ingestion of OHM contaminated food (ADD_{fi}) may be calculated. The general form for this equation may be applied to ingestion of contaminated fish, meat, or vegetables.

$$ADD_{fi} = \frac{[OHM]_f * FI * BAF * F * D_1 * D_2 * C}{BW_{avg} * AP}$$

Where:

$[OHM]_f$ = Representative concentration of OHM in the food of concern during the period of exposure (dimensions: mass/mass)
FI = Daily intake of the food of concern on days exposed during the exposure period (dimensions: mass/event)
BAF = Bioavailability Adjustment Factor
F = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)
D_2 = Duration of the exposure period (dimension: time)
BW_{avg} = Average body weight of the receptor of concern during the averaging period (dimension: mass)
AP = Averaging Period (dimension: time)
C = Appropriate units conversion factor(s)

7. Mother's Milk

The Average Daily Dose of OHM received via ingestion of mother's milk (ADD_{mm}) may be significant as this is often the sole food source for infants and lipophilic contaminants tend to concentrate in the mother's milk..

$$ADD_{mm} = \frac{[OHM]_{mm} * VM * BAF * D_2 * C}{BW_{avg} * AP}$$

Where:

$[OHM]_{mm}$ - Representative concentration of OHM in the mother's milk during the exposure period (dimensions: mass/volume)

VM - Daily volume of mother's milk ingested by the infant during the exposure period (dimensions: volume/time)

BAF - Bioavailability Adjustment Factor

D_2 - Duration of the exposure period (dimension: time)

BW_{avg} - Average body weight of the infant during the averaging period (dimension: mass)

AP - Averaging Period (dimension: time)

C - Appropriate units conversion factor(s)

F. DEVELOPMENT OF EXPOSURE PROFILES

This section applies only to assessments conducted per Method 3.b. For Methods 1, 2 and 3.a., exposure point concentrations are compared to standards, clean-up levels, guidelines or policies. "Exposure profiles" need not be developed for Methods 1, 2, and 3.a., as a separate receptor is assumed to be present at each exposure point. However, for Method 3.b., a calculation of total site risk(s) is required. Each calculation is to be based on the exposure pattern for a single theoretical individual or group of individuals.

For Method 3.b., exposure point concentrations are compared to standards and in addition, total risks to an individual posed by the disposal site are estimated and compared to total site risk limits. Estimation of total risks involves estimation of daily doses to a receptor at each exposure point. It should be assumed that a single theoretical receptor is exposed to OHM at all exposure points unless it is demonstrated that this is not the case. When more than one theoretical receptor is necessary to "cover" all the exposure points then an exposure profile should be developed for each of the theoretical receptors. A separate risk characterization should be conducted for each theoretical receptor.

The exposure profile would include a narrative description of each potential receptor and the activity(-ies) which could potentially lead to exposure(s) to OHM at or from the disposal site. It is important to realize that a theoretical receptor may experience exposures at several locations at or around the site. In addition, these exposures may occur under present site conditions, under foreseeable future use conditions OR UNDER A COMBINATION OF THE TWO. A theoretical receptor may also experience potentially harmful acute, subchronic, chronic and lifetime exposures. Each combination would have to be described and evaluated as a separate exposure profile.

EXAMPLE: Chemical A has been reported at high levels in a residential neighborhood. Among the exposure profiles which may be developed for the risk assessment may be ones which concern:

1. A child who may experience a high, one-day worst-case dose of chemical A via ingestion of the contaminated soil. An Average Daily Dose for the acute exposure would be estimated and compared to the appropriate toxicity value.

2. A child who may experience a 10 year exposure to chemical A via incidental ingestion of soil, inhalation of volatilized material and ingestion of the contaminated groundwater. Perhaps both a Lifetime Average Daily Dose (for carcinogenic effects) and a Chronic Average Daily Dose (AP = 10 years, for non-carcinogenic effects) would have to be estimated and evaluated.

A complete exposure profile for an individual would consist of the following:

1. Identification and description of the receptor for whom the profile is being developed and the activities at or near the disposal site which may lead to potential exposures.

2. Identification of all exposure points at which the theoretical receptor may come into contact with the OHM.

3. Identification of all the OHM and their concentrations at each exposure point.

4. Identification of routes of exposure at each exposure point for each OHM.

5. Identification of magnitude (average daily dose), frequency and duration of exposure for each OHM in each route of exposure at each exposure point currently and in the foreseeable future.

The exposure profile developed for the Phase II Risk Characterization will not necessarily be the same as the exposure profile used in Phase III to demonstrate that the selected remedy meets the risk requirements set forth in 310 CMR 40.545(3)(i). For example, the selected remedy may change the future land use at an exposure point, requiring a completely different exposure scenario.

V. RISK CHARACTERIZATION

The specific risk characterization procedure depends upon the evaluation Method chosen for the disposal site. In general, Risk Characterization compares exposure point concentrations to applicable standards and guidelines and quantifies the risks of carcinogenic and noncarcinogenic health effects. These risks are compared to regulatory risk limits in order to evaluate the need for remediation.

Remediation is required if a significant risk of harm to health, safety, public welfare or the environment does or would exist if the disposal site were to remain unremediated into the foreseeable future. Conditions which represent a significant risk include those where applicable standards, guidelines, policies or risk limits are exceeded.

N.B.- While remediation may be required at a particular disposal site, it should not be automatically assumed that the exceedance of a standard, guideline, policy or risk limit has or will result in adverse health effects. As described in 310 CMR 40.545(3), the methodology presented to characterize risk at a c.21E disposal site is primarily a tool for the determination of whether or not further remedial response action is necessary. The risk assessment cannot predict or establish any actual cause-and-effect relationship between environmental contamination and an individual's or community's health. While the assessment estimates the likelihood of carcinogenic and noncarcinogenic health effects, it is not intended as a substitute for an epidemiologic study designed to assess the health status of a community. A full scale health assessment, including medical and physical testing and biomonitoring, may be conducted to determine whether specific individuals have experienced exposures and/or adverse health effects. Even then, cause-and-effect relationships are difficult to establish. These activities are not within the scope of the MCP Phase II Risk Characterization process.

Remedial response action is generally necessary based upon the risk of harm to health if the requirements of 310 CMR 40.545(3)(i)2. are not met. The remedial response alternative recommended in Phase III shall, when implemented, achieve compliance with the requirements of 310 CMR 40.545(3)(j).

The following sections describe the risk characterization procedure for each of the Methods described in this guidance. ONLY ONE RISK CHARACTERIZATION PROCEDURE WILL APPLY TO A GIVEN DISPOSAL SITE. A statement must be included in the Phase II Risk Characterization regarding the need for further remedial response action pursuant to 310 CMR 40.545(3)(i).

A. RISK CHARACTERIZATION PER METHOD 1 - 310 CMR 40.545(3)(g) 1.

This section applies to sites evaluated using Method 1. All current and reasonably foreseeable exposure point concentrations for each OHM at each exposure point (per 40.545(3)(d)) are compared to the corresponding applicable or suitably analogous public health standards. Any current or reasonably foreseeable exposure point concentrations which exceed corresponding standards should be identified. Lists of potentially applicable or suitably analogous standards appear in Appendix C.

CONCLUSIONS:

The conclusions of the risk characterization should clearly identify any and all current and reasonably foreseeable exposure point concentrations which exceed corresponding applicable or suitably analogous public health standards under baseline conditions. If no exposure point concentration exceeds a corresponding applicable or suitable analogous public health standard then no remedial response action is necessary to satisfy the public health component of 310 CMR 40.545(3)(i).

B. RISK CHARACTERIZATION PER METHOD 2 - 310 CMR 40.545(3)(g) 2.

This section applies only to disposal sites evaluated by Method 2. All current and reasonably foreseeable exposure point concentrations (40.545(3)(d)) and site conditions are compared to the corresponding clean-up levels which are contained in the appropriate set of clean-up levels which appear in 310 CMR 40.800. Any current or reasonably foreseeable exposure point concentrations or site conditions which exceed corresponding clean-up levels should be identified.

CONCLUSIONS:

The conclusions of the risk characterization should clearly identify any and all current and reasonably foreseeable exposure point concentrations which exceed corresponding values in the specific set of clean-up level. If no exposure point concentration exceeds a clean-up level in the specific set of clean-up levels applicable to the disposal site then no remedial response action is necessary to satisfy the public health component of 310 CMR 40.545(3)(i).

C. RISK CHARACTERIZATION PER METHOD 3.a. - 310 CMR 40.545(3)(g) 3.a.

This section applies only to disposal sites evaluated by Method 3.a. Each current and reasonably foreseeable exposure point concentrations for each OHM at each exposure point are compared to an applicable or suitably analogous standards where one exists (lists of standards appear in Appendix C) and, if one does not exist, to a health or risk-based guideline or requirement of policy where they exist (lists of guidelines and policies appear in Appendices D & E respectively). Where no standard, guideline or policy is available for a given OHM in a given medium, a guideline should be developed and proposed by the PRP or other party when sufficient toxicological information is available. Such guidelines should be developed using guidance contained in Appendix A, "Development of Health/Risk-Based Guidelines."

CONCLUSIONS:

Any current or reasonably foreseeable exposure point concentrations which exceed corresponding standards, guidelines or requirements of Departmental policies should be identified. If no exposure point concentration exceeds any corresponding standard, guidelines, or requirements of Departmental policies then no remedial response action is necessary to satisfy the public health component of 310 CMR 40.545(3)(i).

D. RISK CHARACTERIZATION PER METHOD 3.b. - 310 CMR 40.545(3)(g) 3.b.

This section applies only to disposal sites evaluated by Method 3.b. Each current and reasonably foreseeable exposure point concentration for each OHM at each exposure point are compared to each corresponding applicable or suitably analogous public health standard. Any current or reasonably foreseeable exposure point concentrations which exceed corresponding standards should be identified. Lists of potential applicable or suitably analogous standards appear in Appendix C.

In addition, the total site risks should be characterized in a way that is directly comparable to the Total Site Risk Limits specified in 310 CMR 40.545(3)(g) 3.b. and described below. The total site risks are characterized for the theoretical individual for whom an exposure profile has been generated. Both threshold and non-threshold health effects risks must be characterized for each OHM.

1. Threshold Health Effects

Threshold health effects risks should be characterized by the use of Hazard Indices. The following process is to be applied to each exposure profile identified in Section IV.F - Development of Exposure Profiles. Separate calculations may be required for the characterization of risk for acute, subchronic, chronic and/or lifetime exposures if these have been identified as exposure periods of concern in the development of the exposure profiles.

An initial screening Hazard Index is calculated with doses for all OHM in all exposure routes at all exposure points for the theoretical individual and the exposure period which are the focus of the risk characterization. If the screening Hazard Index has a value less than or equal to the total site non-cancer risk limit (Hazard Index = 0.2, as cited in the regulations: 310 CMR 40.545(3)(g)3.b.), no additional effort is required to characterize threshold effects risks.

N.B.- Generally, a Hazard Index of 1.0 is believed to be a value at or below which it is unlikely that adverse health effects will occur. The MCP has established a total site non-cancer risk limit, as represented by a hazard index, of 0.2. Exposures related to a disposal site are allowed to

contribute only 20% of an estimated allowable daily dose. This level was chosen in consideration of the fact that individuals may experience exposures to the same OHM from sources other than the disposal site. These exposures may include possible dietary and occupational exposures. The approach taken by the Department is similar to that used by the US EPA Office of Drinking Water to develop drinking water standards and health advisories. The EPA ODW apportions 20% of the allowable daily dose to drinking water sources. Given that non-site related exposures are largely untransferable, including large individual variation, the DEQE believes that a Hazard Index limit of 0.2 is protective of the public health.

If the screening Hazard Index is greater than 0.2, a more detailed analysis is required. The OHM should then be divided into groups which share the same or similar mechanism of action, and a separate Hazard Index should be calculated for each group of OHM. The health basis (target organ, health endpoint, or mechanism of action) for the RfD (or other toxicity value used) should serve as a criterion used to group the OHM, although consideration may also be given to other identified health effects associated with a chemical. This information will have been included as part of the Toxicity Profile described in Section II.B.

The Hazard Index is calculated:

$$\text{Hazard Index} = ADD_1/AD_1 + ADD_2/AD_2 + \ldots + ADD_i/AD_i$$

Where:

AD_i - The acceptable daily dose for exposure to substance i. This value will generally be the dose associated with the EPA's Reference Dose (RfD) for most exposure routes and the DEQE's Allowable Threshold Concentration (ATC) (Appendix J) for air exposures. Alternative values which may be used in the absence of an RfD or ATC (or when their use would not be considered appropriate) are discussed in Section III - Dose-Response Assessment.

ADD_i - The daily dose of substance i via the particular exposure route. This value is calculated from the exposure point concentration using exposure assumptions consistent with the site-specific conditions. (SEE Section IV.E. - Estimation of Average Daily Dose and Appendix B - Suggested Default Exposure Assumptions)

The Hazard Indices calculated for each exposure profile identified in Section IV.F. are compared to the total Site Non Carcinogenic Risk Limit (Hazard Index = 0.2).

2. Non-Threshold Health Effects

The risks associated with non-threshold health effects shall be characterized by focusing on estimated excess lifetime cancer risk for the theoretical individual for which an exposure profile has been developed. The total site cancer risk will be calculated by summing the estimated excess lifetime cancer risks associated with the theoretical individual's exposure, over the next 70 years, to OHM which are and/or will be present in all relevant media at all exposure points.

This procedure will generally be performed for Class A & B carcinogens only. An Excess Lifetime Cancer Risk may be calculated for Class C Carcinogens included in the discussion of uncertainties in the risk characterization (See Section VII). Inclusion of Class C carcinogens in the estimation of Total Site Cancer Risk is considered a conservative methodology which may be warranted on a site-by-site basis.

$$\text{Total Site Cancer Risk} = \sum(ELCR_i)$$

- and -

$$ELCR_i = (LADD_i)q_{1i}^*$$

OR:

$$ELCR_i = (LAC_i)UR_i$$

Where:

Total Site Cancer Risk: the sum of all the estimated Excess Lifetime Cancer Risks associated with the individual resulting from exposures to all OHM in all the appropriate media via all exposure pathways.

$ELCR_i$ = Excess Lifetime Cancer Risk associated with the exposure to chemical i in each relevant medium.

$LADD_i$ = Lifetime average daily dose of substance i in each medium received by the theoretical individual. (See Section IV.E. - Estimation of Average Daily Dose)

q_{1i}^* = EPA's Cancer Assessment Group's published cancer slope value for substance i in the appropriate medium. This value can be found in EPA's IRIS database. (See discussion, SECTION III. - Dose-Response Assessment)

LAC_i = The Lifetime Average Concentration of substance i in the relevant medium to which the hypothetical receptor is exposed.

UR_i = EPA's Cancer Assessment Group's published carcinogenic Unit Risk for substance i in the appropriate medium. This value can be found in the EPA's IRIS database. (See discussion, SECTION III. - Dose-Response Assessment)

The Total Site Cancer Risk would be estimated for all Class A & B (and possibly C) OHM in all exposure routes at all exposure points for the theoretical individual who is the focus of the risk characterization.

The Total Site Cancer Risk calculated for each exposure profile identified in Section F is compared to the total Site Cancer Risk Limit of 1×10^{-5} (as cited in the the MCP: 310 CMR 40.545(3)(g)3.b.).

3. <u>SIGNIFICANT FIGURES</u>

In reporting a Hazard Index or Total Site Cancer Risk, the number of significant figures contained in the estimate should be consistent with the data used to calculate that value. The number of significant figures in a value denotes the accuracy of that measure. ("Accuracy" being the

nearness of the measure to the actual value of the variable being measured.) In light of the discussion of uncertainty inherent in the risk characterization process, care should be taken when expressing the total site risk estimates (both carcinogenic and non-carcinogenic). The use of several significant figures (reporting a Hazard Index = 0.42987, or an Total Site Cancer Risk = 4.2987×10^{-5}, for example) implies a level of accuracy which may not be warranted. The number of significant figures should never exceed that of the least accurate measure used in the calculation, including both the measured data and the exposure assumptions drawn from the literature.

4. Shortcuts

Under certain circumstances it may be possible to substantially reduce the amount of time and money necessary to conduct a Method 3.b. risk assessment.

EXAMPLE: Someone might wish to demonstrate that remediation is not necessary at a disposal site by using worst-case data inputs and worst-case assumptions to show that the resulting risks are not significant. To do this, one might assign the toxicity values for the clearly most toxic substance at a disposal site to all substances at the site and use the maximum reported concentrations for each substance in the risk calculations. Under these conditions, if the estimated risks are not significant, then clearly remediation would not be required based upon risk of harm to human health.

EXAMPLE: Someone might wish to demonstrate through a worst-case example that certain exposure pathways result in risks which are orders of magnitude lower than the total site risk limits. Such a demonstration could justify the elimination of that pathway from consideration in the risk characterization.

Other shortcuts, if they are logical, clearly identified and defensible (usually with a quantitative demonstration) should be utilized as well. Eliminating obvious potential exposure pathways without quantitative justification would generally be inappropriate. These shortcuts, and ones like them are encouraged. It is advisable however, to discuss their use with the Department staff before the risk characterization is submitted for approval.

CONCLUSIONS:

Any exposure point concentration which exceeds an applicable or suitably analogous public health standard must be identified. Any Hazard Index greater than 0.2 and any Total Site Cancer Risk greater than 1×10^{-5} must also be identified.

No remedial response action is necessary if all of the following apply:

1. No exposure point concentration exceeds an applicable or suitably analogous public health standard

AND

2. No Hazard Index exceeds the Total Site Non-Carcinogenic Site Risk Limit of 0.2

AND

3. No Total Site Cancer Risk is greater than the Total Site Cancer Risk Limit of 1×10^{-5}.

VI. SAFETY, PUBLIC WELFARE AND ENVIRONMENTAL RISK CHARACTERIZATION

Extensive guidance in this area is not presently available. However, the risks to safety, public welfare and the environment are very important and must be addressed at each disposal site. Health risk assessment cannot be the sole decision-making tool concerning the need for remediation at a disposal site.

Remedial response action is generally necessary based upon the risk of harm to safety, public welfare and the environment if the requirements of 310 CMR 40.545(3)(i)1. are not met. The remedial response alternative recommended in Phase III shall, when implemented, achieve compliance with the requirements of 310 CMR 40.545(3)(j).

At a minimum, current and reasonably foreseeable disposal site conditions and conditions in the surrounding environment must be compared to applicable or suitably analogous safety, public welfare and environmental standards, guidelines and policies.
(See Appendices C, D, E).

CONCLUSIONS:

Any site conditions or conditions in the surrounding environment which are caused by the OHM at or from disposal site which do not comply with safety, public welfare and environmental standards, guidelines and policies must be identified. If all site conditions and conditions in the surrounding environment which are caused by OHM at or from the disposal site comply with safety, public welfare and environmental standards, guidelines and policies no further remedial action is required to satisfy the requirements of 310 CMR 40.545(3)(i)1.

VII. UNCERTAINTY ANALYSIS

The risk characterization performed as part of the Phase II Investigation, as in all risk assessments, is subject to a wide variety of uncertainties. As a result, the risk estimates derived should not be interpreted as absolute estimates of the risk of harm to health, safety, welfare or the environment. These estimates are the result of a conservative, consistent analysis intended to evaluate the potential for adverse impacts. They are not predictors of such impacts.

Uncertainty may be introduced at each step of the risk characterization process. General sources of uncertainty include:

- sampling of the environmental media
- modeling of the exposure point concentrations
- development of the toxicological data, including the dose-response value
- development of the exposure profiles
- choice of the exposure assumptions used in the calculations

The risk characterization should include a discussion of of the uncertainties particular to the assessment being submitted as part of the Phase II Report.

VIII. SUGGESTED OUTLINE FOR PHASE II REPORT - RISK CHARACTERIZATION

Following is a list of activities which should be performed in order to adequately characterize risks at a given disposal site. Not all sections apply to each risk characterization method. This list may serve as the outline for the risk characterization portion of the Phase II Report.

I. Identification of current and reasonably foreseeable land use

II. Hazard Identification

- A. Identification of extent of release of OHM
- B. Toxicity Profiles or descriptive summaries as appropriate

III. Dose-Response Assessment

IV. Exposure Assessment

- A. Identification of Potential Human Receptors
- B. Identification of Exposure Points
- C. Identification of Exposure Routes
- D. Identification/Estimation of Exposure Point Concentrations
  1. Selection of Analytical Data
  2. Treatment of Non-Detects and Trace Values
  3. Calculating Exposure Point Concentrations
  4. Modeling of Exposure Point Concentrations

V. Identification of applicable or suitably analogous public health standards, guidelines, policies, and sets of clean-up levels.

VI. Selection of Method for Conducting Risk Assessment

VII. Estimation of Average Daily Doses (where appropriate)

VIII. Development of Exposure Profiles (where appropriate)

IX. Development and proposal of health-based guidelines (Method 3.a. only)

X. Risk Characterization

XI. Identification of potential applicable or suitably analogous environmental standards, guidelines and policies

XII. Characterization of risk of harm to the environment

XIII. Characterization of risk of harm to safety

XIV. Characterization of risk of harm to public welfare

XV Uncertainty Analysis

XVI. Conclusion related to 40.545(3)(i)

APPENDIX A

DEVELOPMENT OF HEALTH/RISK-BASED GUIDELINES

Health/Risk-Based Guidelines

Health/Risk-based guidelines shall be developed per 310 CMR 40.545 (3)(g) 3.a. by using standard exposure assumptions and dose-response information and toxicity constants available from EPA's IRIS database. Guidelines should be developed such that the resultant daily dose from lifetime exposure to the guideline concentration would not be associated with significant threshold or non-threshold health effects. Therefore, the daily dose would need to be less than or equal to 20% of the EPA's Reference Dose or another acceptable daily intake specified by the Department or one calculated using methods specified by the Department. The daily dose should also be less than or equal to the daily dose associated with an excess lifetime cancer risk of one in one million. That dose can be calculated as:

$$\text{Daily Dose (mg/kg/day)} = \frac{1 \times 10^{-6}}{q_1^*}$$

Where:

1×10^{-6} = allowable excess lifetime cancer risk for a single chemical via a single exposure route.

q_1^* = EPA's Cancer Assessment Group's published cancer slope value. This number is actually the upper 95% confidence limit of the slope. It has units $(mg/kg/day)^{-1}$

Daily Dose = daily dose associated with an excess lifetime cancer risk of one in one million.

Guidelines for contaminants in ambient air shall be calculated using CHEM & AAL (DEQE, 1989).

When using Method 3.a., in certain circumstances, a search for applicable or suitably analogous guidelines may identify guidelines which were developed for the appropriate OHM and medium but for an inappropriate duration and/or frequency of exposure.

EXAMPLE: An ambient air guideline for toluene, developed for continuous lifetime exposure is identified, but the exposure under evaluation is 40 hours per week for a lifetime.

Under such circumstances, it may be appropriate to propose guidelines adjusted for the frequency and duration of exposure under investigation.

EXAMPLE: If the toluene air guideline was based on a chronic toxicity endpoint and the guideline assumes a continuous lifetime exposure, the guideline may be "adjusted" for the 40-hour per week as follows:

$$\text{"adjusted guideline"} = \text{toluene guideline} \times \frac{168 \text{ hours}}{\text{week}} \times \frac{1 \text{ week}}{40 \text{ hours}}$$

"adjusted guideline" = 4.2 X toluene guideline

Extreme care must be taken when making such adjustments to insure that the resulting "adjusted guideline" remains consistent with the available toxicity information. If the existing guideline is based upon reproductive toxicity, for example, such adjustments should not be made.

APPENDIX B

SUGGESTED DEFAULT EXPOSURE ASSUMPTIONS

I. EXPOSURE ASSUMPTIONS

This Appendix lists Default Exposure Assumptions which may be used in the Exposure Assessment to calculate dose. In the absence of site specific, or otherwise justifiable exposure information, the following values should be used to provide realistic yet adequately conservative dose calculations. The selection of the Exposure Assumptions should be described in narrative form, accompanied by a referenced summary table.

References have been provided below for additional values and background information.

Assumptions for frequency of exposure are not contained here. The frequency of exposure should be determined on a site-by-site basis wherever possible, and any assumptions used should be clearly stated and reflect unique site conditions.

A. AVERAGE BODY WEIGHTS (BW_{avg})

Adult.....70 kg
Child.....10 kg

- US EPA, Office of Emergency and Remedial Response, Superfund Public Health Evaluation Manual, EPA 540/1-86/060, October 1986

SEE ALSO:

- Anderson E, Browne N, Duletsky S, et al., Development of Statistical Distributions or Ranges of Standard Factors Used in Exposure Assessments, US EPA Office of Health and Environmental Assessment, Washington D.C., EPA/600/8-85/010, August 1985

B. SKIN SURFACE AREA (SA)

CHILD: (age 2-3 years)

Total.....0.603 m^2 Male
.....0.579 m^2 Female

Arms.....0.071 m^2
Hands.....0.032 m^2
Legs.....0.140 m^2
Feet.....0.043 m^2

ADULT: Total.....1.94 m^2 Male
.....1.69 m^2 Female

Arms.....0.291 m^2
Hands.....0.099 m^2
Legs.....0.640 m^2
Feet.....0.131 m^2

- Anderson E, Browne N, Duletsky S, et al., Development of Statistical Distributions or Ranges of Standard Factors Used in Exposure Assessments, US EPA Office of Health and Environmental Assessment, Washington D.C., EPA/600/8-85/010, August 1985

C. SOIL INGESTION RATE (I)

(Rate of Ingestion on days exposed)

Age	Ingestion Rate (mg of soil/day)
0-1 years	50
1-6 years	100
6-11 years	50
> 11 years	50

- LaGoy, P.K., "Estimated Soil Ingestion Rates For Use In Risk Assessment", Risk Analysis, Vol 7 No 3, 1987

SEE ALSO:

Binder S, Sokal D, and Mangham D, "Estimating Soil Ingestion: The Use of Tracer Elements In Estimating the Amount of Soil Ingested By Young Children" Archives of Environmental Health, Vol 41, 1986, pp. 341-345

Clausing P, Brunekreef B, and van Wijnen JH, "A Method For Estimating Soil Ingestion By Children", International Archives For Occupational and Environmental Health, Vol 59, 1987, pp. 73-82

Hawley, J.K., "Assessment of Health Risk from Exposure to Contaminated Soil", Risk Analysis, Vol. 5, No 4, 1985

D. VOLUME OF DRINKING WATER INGESTION (VI)

Adult.....2 Liters/day
Child.....1 Liter/day

- US EPA, Office of Emergency and Remedial Response, Superfund Public Health Evaluation Manual, EPA 540/1-86/060, October 1986

SEE ALSO:

Methods for Assessing Exposure to Chemical Substances, Vol 5, Methods for Assessing Exposure to Chemical Substances in Drinking Water, US EPA, Office of Toxic Substances, Washington D.C., EPA/560/5-85/005, August 1985

E. DAILY RESPIRATORY VOLUME (VR)

Adult.....20 m^3/day
Child.....10 m^3/day

- "A Summary of Ventilation Rates as a Function of Age, Sex, Physical Activity, Climate, Conditions and General Health State", Report No. UCRL 89037, Lawrence Livermore National Laboratory, Livermore CA 1983

SEE ALSO:

US EPA, Office of Emergency and Remedial Response, Superfund Public Health Evaluation Manual, EPA 540/1-86/060, October 1986

Anderson E, Browne N, Duletsky S, et al., Development of Statistical Distributions or Ranges of Standard Factors Used in Exposure Assessments, US EPA Office of Health and Environmental Assessment, Washington D.C., EPA/600/8-85/010, August 1985

F. AIRBORNE PARTICULATE CONCENTRATION $[PM_{10}]_{air}$

$[PM_{10}]_{air}$ = 44 ug/m^3 maximum Annual Mean recorded in Massachusetts (1986)

- MA DEQE, Division of Air Quality Control, 1986 Air Quality Report, November 1987

SEE ALSO:

40 CFR Chapter 1 Section 50.6 (a.) & (b.), National Ambient Air Quality Standards

Spengler, J.D. and Thurston, G.D., "Mass and Elemental Composition of Fine and Course Particles in Six US Cities", Journal of the Air Pollution Control Association, Vol 33, 1983, pp. 1162-1171

G. DERMAL ABSORPTION FACTOR (AF)

OHM in Soil:

	range
VOCs	10 - 25%
SVOCs	1 - 10%
Pesticides	1 - 10%
Inorganics	0.1 - 1%

- Ryan, E.A., Hawkins, E.T., Magee, B., Santos, S.L., "Assessing Risk From Dermal Exposure At Hazardous Waste Sites", Superfund '87 Proceedings of the 8th National Conference, November 16-18, 1987, Washington D.C., Sponsored by the Hazardous Materials Control Research Institute

SEE ALSO:

Yang, J.J., Roy, T.A., Krueger, A.J., Neil, W., and Mackerer, C.R., "Bioavailability of Chemical Contaminants in Soil: Percutaneous Absorption of Benzo[a]pyrene in Crude Oil and Soil-Sorbed Crude Oil in the Rat", presented at the International Symposium on Chemical Mixtures, Cincinnati OH, June 1988

H. SOIL ADHERENCE MASS (MS)

The mass of soil adhering to a unit surface area of exposed skin

MS = 0.51 mg soil/cm^2 skin

- Hawley, J.K., "Assessment of Health Risk From Exposure to Contaminated Soil", Risk Analysis, Vol 5, 1985 pp. 289-302

SEE ALSO:

Harger, J.R.E., "A Model for the Determination of an Action Level for Removal of Curene Contaminated Soil" Memorandum to P.S. Cole, Executive Director, Toxic Substance Control Commission, Lansing MI, October 25, 1979

Kimbrough, et al., "Health Implications of 2,3,7,8-TCDD Contamination of Residual Soil", Journal of Toxicology and Environmental Health, 14:47-93, 1984

I. FOOD CONSUMPTION (FI)

1. Seafood

Daily Intake of Seafood = 20 g/day

- Guidance Manual for Health Risk Assessment of Chemically Contaminated Seafood, US EPA Puget Sound Estuary Program, prepared by Tetra Tech, Inc., Bellevue Washington, June 1986

SEE ALSO:

US EPA, Water Quality Criteria Documents: Availability, FR Vol 45, No. 231, Part V, pp. 79318 - 79379, 1980

"Fisheries of the United States, 1983", Current Fishery Statistics No. 8320, US Dept. of Commerce, April 1984

2. Mother's Milk (MM)

Infant's Daily Intake of
Mother's Milk = 696 ml/day

- Radiological Assessment: Predicting the Transport, Bioaccumulation, and Uptake by Man of Radionuclides Released to the Environment, National Council on Radiation Protection and Measurement, NCRP Report No. 76, March 1984

3. Additional Food Intakes

Food Type	Child*	Adult*
Fruit, Vegetable & Grain	548 g/day	521 g/day
Milk	466 ml/day	301 ml/day
Meat & Poultry	101 g/day	260 g/day

* derived from yearly intake values presented

- Radiological Assessment: Predicting the Transport, Bioaccumulation, and Uptake by Man of Radionuclides Released to the Environment, National Council on Radiation Protection and Measurement, NCRP Report No. 76, March 1984

J. NON-INGESTION DRINKING WATER EXPOSURES

In situations where there is not sufficient information to calculate dermal and inhalation doses of OHM associated with household use of drinking water, some assumptions should be made about the magnitude of those exposures.

In general, unless there is evidence which indicates otherwise, exposures via inhalation are important only for volatile organic compounds and known specific volatile materials which are not volatile organic compounds. Inhalation exposures to nonvolatile organic and inorganic substances during household use of drinking water may be assumed to be zero.

For volatile organic compounds, it has been suggested that inhalation exposure to drinking water may result in absorbed doses equal to or greater than doses associated with ingestion exposure (adult 2 liters/day, child 1 liter/day)

- Andelman, J. B., "Inhalation Exposure in the Home to Volatile Organic Contaminants of Drinking Water", The Science of the Total Environment, Vol. 47, 1985, pp. 443-460.

It has also been suggested that dermally absorbed doses of some volatile organic compounds received during bathing and showering may be equal to or greater than the doses received via ingestion of the same water (adult 2 liters/day, child 1 liter/day). When there is insufficient information for calculating dermally absorbed doses of VOCs in drinking water, it may be assumed that the daily dose via dermal absorption is equal to the daily ingested dose (adult 2 liters/day, child 1 liter/day).

- Brown, H.S., Bishop, D.R. and C.A. Rowan, "The Role of Skin Absorption as a Route of Exposure for Volatile Organic Compounds (VOCs) in Drinking Water," American Journal of Public Health, Vol. 74, No. 5, May 1984, pp. 479-484.

Based on the above assumptions, when there is insufficient information for direct calculation of doses of VOCs in drinking water via inhalation and dermal absorption, it may be assumed that the total dose via ingestion, inhalation and dermal absorption is equal to three times the ingested dose.

K. Bioavailability Adjustment Factor (BAF)

The dose calculation equations presented in Section IV.E. of this document incorporate Bioavailability Adjustment Factors (BAF) which must be determined or estimated for each chemical via each route of exposure.

The BAF addresses two major issues:

- the absorption efficiency for the route and medium of exposure, and

- the absorption efficiency for the route and medium of exposure for the "experimental study" which is the basis of the Reference Dose or the Potency Value for the chemical in question.

In general (see discussion below), the Bioavailability Adjustment Factor is the ratio of these two values:

$$BAF = \frac{\text{Absorption Efficiency (exposure)}}{\text{Absorption Efficiency (study)}}$$

N.B.- The actual efficiency of absorption of the "free" contaminant via a particular exposure route and the ability of the contaminant to become "free" from the medium or matrix are separate issues that contribute to the bioavailability adjustment factor.

It is important to calculate the daily dose in such a way that it can be appropriately compared to the RfD and be used with the Potency Factor to estimate carcinogenic risk. For example, while it is most appropriate to compare an estimated absorbed dose to an RfD which represents an absorbed daily dose, most RfDs actually represent an APPLIED dose. Care must be taken to insure that the risk assessor does not compare an estimated absorbed daily dose to an applied dose represented by the RfD.

* It is thus necessary to investigate whether an RfD or a Carcinogenic Potency Value is derived from an absorbed or an applied dose in the experimental study. Without this information, potential risks may not be correctly estimated.

EXAMPLE: Chromium VI is reported in the surficial soil at a disposal site. The oral Reference Dose for Chromium VI is 5×10^{-3} mg/kg/day (from the US EPA IRIS database). The documentation for the derivation of the RfD reveals that the oral RfD represents an applied dose of Chromium VI in drinking water for a rat study.

Comparison of this Reference Dose to an absorbed Average Daily Dose would be incorrect. However, the comparison of an applied dermal dose to an applied ingested dose would also be incorrect. An adjustment must be made which would allow for the comparison of the estimated exposure or dose to the RfD which is available.

Casarett and Doull's Toxicology (1986) reports that only 1% of ingested chromium is absorbed. Assuming an estimated absorption efficiency of Chromium VI from soil via dermal contact to be 1% (Ryan et al, 1987), the Bioavailability Adjustment Factor would be the ratio:

$$\frac{\text{Absorption Efficiency of Cr VI from soil via dermal contact}}{\text{Absorption Efficiency of Cr from drinking water ingestion}}$$

or,

$$BAF = \frac{1\%}{1\%} = 1.0$$

THUS:

1. If the RfD represents the APPLIED dose from the animal study, or the Carcinogenic Potency Factor has been derived from an APPLIED dose in the animal study, then the Bioavailability Adjustment Factor (BAF) would equal:

$$BAF = \frac{\text{Absorption Efficiency via route \& medium of exposure}}{\text{Absorption Efficiency via route \& medium in experimental study}}$$

2. If the RfD represents the ABSORBED dose from the animal study, or the Carcinogenic Potency Value has been derived from an ABSORBED dose in the animal study, then the Bioavailability Adjustment Factor (BAF) would equal:

BAF = Absorption Efficiency via the route and medium under consideration. (In other words, the Average Daily Dose calculated would represent an absorbed dose.)

The following page presents a worksheet which could be used to estimate Bioavailability Adjustment Factors.

BAF WORKSHEET

$BAF = \frac{AEx}{AEy}$ or $BAF = AEx$	Reference Dose IF an AEy was used to develop the RfD, then BAF = AEx !! RA: _____	Potency Value IF an AEy was used to develop the Potency Value then BAF = AEx !! RA: _____
Route of Exposure at Disposal Site:	AEy: _____ : estimate of absorption efficiency for study.	AEy: _____ : estimate of absorption efficiency for study.
Soil Ingestion AEx = _____	$\frac{x}{y} =$ _____	$\frac{x}{y} =$ _____
Soil Dermal Contact AEx = _____	$\frac{x}{y} =$ _____	$\frac{x}{y} =$ _____
Water Ingestion AEx = _____	$\frac{x}{y} =$ _____	$\frac{x}{y} =$ _____
Water Dermal Contact AEx = _____	$\frac{x}{y} =$ _____	$\frac{x}{y} =$ _____
Other Exposure Pathway: _____ AEx = _____	$\frac{x}{y} =$ _____	$\frac{x}{y} =$ _____

CHEMICAL: _____

Typical worksheet which may be used to estimate Bioavailibility Adjustment Factors (BAFs).

WHERE: AEx = Absorption Efficiency via the exposure pathway being assessed.
AEy = Absorption Efficiency via the Route of Administration (RA) used in the study to determine the Reference Dose or the Potency Value.
OR AN ESTIMATE OF SUCH A VALUE IF NONE WERE ACTUALLY USED IN THE STUDY.
RA = Route of Administration of the dose in the experimental study.

BAF = AEx/AEy when no absorption efficiency was used to derive the dose/response value.

BAF = AEx when such an absorption efficiency was used.

APPENDIX C

POTENTIALLY APPLICABLE OR SUITABLY ANALOGOUS "STANDARDS"

Appendix C-1

Potentially Applicable or Suitably Analogous

PUBLIC HEALTH STANDARDS

Standards apply in all situations
including methods 1, 2, 3a., and 3b.

DRINKING WATER

All requirements of 310 CMR 22.00 and the 1988 Amendments to 310 CMR 22.00 must be considered, including, but not limited to:

Substance	Maximum Contaminant Levels (mg/l)
Arsenic	0.050
Barium	1.0
Benzene	0.005
Cadmium	0.010
Carbon Tetrachloride	0.005
Chromium (Cr VI)	0.050
2, 4-D	0.100
1,2-Dichloroethane	0.005
1,1-Dichloroethylene	0.007
Endrin	0.0002
Flouride	4.0
Lead	0.050
Lindane	0.004
Mercury	0.002
Methoxychlor	0.100
Nitrate (As N)	10.0
Selenium	0.010
Silver	0.050
Sodium	20.0
Total Trihalomethanes	0.100
Toxaphane	0.005
2,4,5-TP (Silvex)	0.010
1,1,1-Trichloroethane	0.200
Trichloroethylene	0.005
Turbidity	1 Turbidity unit
Vinyl Chloride	0.002
Radium (226 + 228)	5 pCi/Liter
Gross Alpha Particle Activity (excluding U and Rn)	15 pCi/Liter
Beta Particle and Photons	annual dose <4 mrem/yr.

N.B.: 310 CMR 22.00 is frequently revised, with the addition of new chemicals and updates of the MMCLs. The DEQE Division of Water Supply should be consulted for the latest version.

Appendix C-1

Potentially Applicable or Suitable Analogous

PUBLIC HEALTH STANDARDS

Standards apply in all situations including methods 1, 2, 3a and 3b.

Ambient Air

All requirements of 310 CMR 6.00 must be considered, including, but not limited to:

Substance	Maximum Concentrations
Sulfur Oxides measured as Sulfur Dioxide	-80 ug/m^3 (0.03 ppm) (annual arithmetic mean) -365 ug/m^3 (0.14 ppm) (max. 24-hr concentration not to be exceeded more than once per year)
PM_{10}	-50 ug/m^3 (annual arithmetic mean) -150 ug/m^3 (maximum 24-hour concentration not to be exceeded more than once per year)
Carbon Monoxide	-10 mg/m^3 (9 ppm) (max. 8-hr concentration not to be exceeded more than once per year) -40mg/m^3 (35 ppm) (max. 1-hr concentration not to be exceeded more than once per year)
Ozone	-240 ug/m^3 (0.12 ppm) (expected number of days per calendar year with maximum hourly average concentrations above 235 ug/m^3 must be equal to less than one)
Nitrogen Dioxide	-100 ug/m^3 (0.05 ppm) (annual arithmetic mean)
Lead	-1.5 ug/m^3 (calendar quarter)

Concentrations represent primary ambient air quality standards established to protect Public Health

Appendix C-2

Potentially Applicable or Suitably Analogous

ENVIRONMENTAL STANDARDS

All requirements of 314 CMR 4.00 must be considered, including, but not limited to:

Surface Water Standards

Classes for Inland Waters

Class A - Waters assigned to this class are designated for use as a source of public water supply.

Class B - Waters assigned to this class are designated for the uses of protection and propagation of fish, other aquatic life and wildlife; and for primary and secondary contact recreation.

Class C - Waters assigned to this class are designated for the uses of protection and propagation of fish, other aquatic life and wildlife; and for secondary contact recreation.

Classes for Coastal and Marine Waters

Class SA - Waters assigned to this class are designated for the uses of protection and propagation of fish, other aquatic life and wildlife; for primary and secondary contact recreation; and for shellfish harvesting without depuration in approved areas.

Class SB - Waters assigned to this class are designed for the uses of protection and propagation of fish, other aquatic life and wildlife; for primary and secondary contact recreation; and for shellfish harvesting with depuration (Restricted Shellfish Areas).

Class SC - Waters assigned to this class are designated for the protection and propagation of fish, other aquatic life and wildlife; and for secondary contact recreation.

(A) Minimum Criteria. The following minimum criteria are adopted and shall be applicable to all waters of the Commonwealth.

These minimum criteria are applicable to all waters of the Commonwealth, unless criteria specified for individual classes are more stringent.

Parameter	Criteria
1. Aesthetics	All waters shall be free from pollutants in concentrations or combinations that: (a) Settle to form objectionable deposits; (b) Float as debris, scum or other mater to form nuisances; (c) Produce objectionable odor, color, taste or turbidity; or (d) Result in the dominance of nuisance species.
2. Radioactive Substances	Shall not exceed the recommended limits of the United States Environmental Protection Agency's National Drinking Water Regulations.
3. Tainting Substances	Shall not be in concentrations or combinations that produce undesirable flavors in the edible portions of aquatic organisms.
4. Color, Turbidity, Total Suspended Solids	Shall not be in concentrations or combinations that would exceed the recommended limits on the most sensitive receiving water use.
5. Oil and Grease	The water surface shall be free from floating oils, grease and petrochemicals and any concentrations or combinations in the water column or sediments that are aesthetically objectionable or deleterious to the biota are prohibited. For oil and grease of petroleum origin the maximum allowable discharge concentration is 15 mg/l.
6. Nutrients	Shall not exceed the site-specific limits necessary to control accelerated or cultural eutrophication.

	Parameter	Criteria
7.	Other Constituents	Waters shall be free from pollutants in concentrations or combinations that (a) Exceed the recommended limits on the most sensitive receiving water use; (b) Injure, are toxic to, or produce adverse physiological or behavioral responses in humans or aquatic life; or (c) Exceed site-specific safe exposure levels determined by bioassay using sensitive resident species.

(B) Inland Waters - the following additional minimum criteria are applicable to inland water classifications.

For Class A waters:

	Parameter	Criteria
1.	Dissolved Oxygen	Shall be a minimum of 5.0 mg/l in warm water fisheries and a minimum of 6.0 mg/l in cold water fisheries.
2.	Temperature	Shall not exceed 83°F (28.3°c) in warm water fisheries or 88°F (20°c) in cold water fisheries nor shall the rise resulting from artificial origin exceed 4.0°F (2.2°c).
3.	pH	As naturally occurs.
4.	Total Coliform Bacteria	Shall not exceed a log mean for a set of samples of 50 per 100 ml during any monthly sampling period.

5.	Turbidity	None other than of natural origin.
6.	Total Dissolved Solids	Shall not exceed 500 mg/l.
7.	Chlorides	Shall not exceed 250 mg/l.
8.	Sulfates	Shall not exceed 250 mg/l.
9.	Nitrate	Shall not exceed 10 mg/l as nitrogen.

For Class B waters:

	Parameter	Criteria
1.	Dissolved Oxygen	Shall be a minimum of 5.0 mg/l in warm water fisheries and a minimum of 6.0 mg/l in cold water fisheries.
2.	Temperature	Shall not exceed 83°F (28.3°C) in warm water fisheries or 68°F (20°C) in cold water fisheries, nor shall the rise resulting from artificial origin exceed 4.0°F (2.2°C).
3.	pH	Shall be in the range of 6.5-8.0 standard units and not more than 0.2 units outside of the naturally occurring range.
4.	Fecal Coliform Bacteria	Shall not exceed a log mean for a set of samples of 200 per 100 ml, nor shall more than 10% of the total samples exceed 400 per 100 ml during any monthly sampling period, except as provided in 314 CMR 4.02(1).

For Class C waters:

	Parameter	Criteria
1.	Dissolved Oxygen	Shall be a minimum of 5.0 mg/l in warm water fisheries and a minimum of 6.0 mg/l in cold water fisheries.
2.	Temperature	Shall not exceed 83°F (28.3°C) in warm water fisheries or 68°F (20°C) in cold water fisheries, nor shall the rise resulting from artificial origin exceed 4.0°F (2.2°C).
3.	pH	Shall be in the range of 6.5-9.0 standard units and not more than 0.2 units outside of the naturally occurring range.
4.	Fecal Coliform Bacteria	Shall not exceed a log mean for a set of samples of 1000 per 100 ml, nor shall more than 10% of the total samples exceed 2,500 per 100 ml during any monthly sampling period, except as provided in 314 CMR 4.02(1).

(C) -Coastal and Marine Waters - the following additional minimum criteria are applicable to coastal and marine waters.

For Class SA waters:

	Parameter	Criteria
1.	Dissolved Oxygen	Shall be a minimum of 85 percent of saturation at water temperatures above 77°F (25°C) and shall be a minimum of 6.0 mg/l at water temperatures of 77°F (25°C) and below.
2.	Temperature	None except where the increase will not exceed the recommended limits on the most sensitive water use.

For Class SA waters (cont.):

3.	pH	Shall be in the range of 6.5-8.5 standard units and not more than 0.2 units outside of the naturally occurring range.
4.	Total Coliform Bacteria	Shall not exceed a median value of 70 MPN per 100 ml and not more than 10% of the samples shall exceed 230 MPN per 100 ml in any monthly sampling period.

For Class SB waters:

	Parameter	Criteria
1.	Dissolved Oxygen	Shall be a minimum of 85 percent of saturation at water temperatures above 77°F (25°C) and shall be a minimum of 6.0 mg/l at water temperatures of 77°F (25°C) and below.
2.	Temperature Increase	None except where the increase will not exceed the recommended limits on the most sensitive water use.
3.	pH	Shall be in the range of 6.5-8.5 and not more than 0.2 units outside of the naturally occurring range.
4.	Total Coliform Bacteria	Shall not exceed a median value of 700 MPN per 100 ml and not more than 20% of the samples shall exceed 1000 MPN per 100 ml during any monthly sampling period, except as provided in 314 CMR 4.02(1).

For Class SC waters:

	Parameter	Criteria
1.	Dissolved Oxygen	Shall be a minimum of 85 percent of saturation at water temperatures above 77°F (25°C) and shall be a minimum of 6.0 mg/l at water temperatures of 77°F (25°C) and below.
2.	Temperature Increase	None except where the increase will not exceed the recommended limits on the most sensitive water use.
3.	pH	Shall be in the range of 6.5-8.5 standard units and not more than 0.2 units outside of the naturally occurring range.
4.	Fecal Coliform Bacteria	Shall not exceed a log mean for a set of samples of 1000 MPN per 100 ml, nor shall more than 10% of the total samples exceed 2500 MPN per 100 ml during any monthly sampling period, except as provided in 314 CMR 4.02(1).

Appendix C-2

Potentially Applicable or Suitably Analogous

ENVIRONMENTAL STANDARDS

Standards apply in all situations, including methods 1, 2, 3a and 3b

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All requirements of 310 CMR 6.00 must be considered, including, but not limited to:

Ambient Air Standards

Substance	Maximum Concentrations *
Sulfur Oxides measured as Sulfur Dioxide	-1,300 ug/m^3 (0.5 ppm) (maximum 3-hour concentration not to be exceeded more than once per year)
PM_{10}	-150 ug/m^3 (maximum 24-hour concentration not to be exceeded more than once per year) -50 ug/m^3 (annual arithmetic mean concentration)
Carbon Monoxide	-40 mg/m^3 (35 ppm) (maximum 1-hour concentration not to be exceeded more than once per year) -10 mg/m^3 (9 ppm) maximum 8-hour concentration not to be exceeded more than once per year)
Ozone	-240 ug/m^3 (0.12 ppm) (expected number of days per calendar year with maximum hourly average concentrations above 235 ug/m^3 is equal to less than one)
Nitrogen Dioxide	-100 ug/m^3 (0.05 ppm) (annual arithmetic mean)
Lead	-1.5 ug/m^3 (calendar quarter)

* Concentrations represent secondary ambient air quality standards established to protect public welfare.

Appendix C-2

Potentially Applicable or Suitably Analogous

ENVIRONMENTAL STANDARDS

Standards apply in all situations,
including methods 1, 2, 3a and 3b.

All requirements of 314 CMR 6.00 must be considered, including, but not limited to:

Groundwater Standards

Table 1 of this appendix list the Minimum Ground Water Quality Criteria as they appear in 314 CMR 6.06. In addition, the Table 2 lists additional standards used by the Department per 314 CMR 6.07.

TABLE I - GROUND WATER STANDARDS
314 CMR 6.06

Minimum Ground Water Quality Criteria

(1) Class I and Class II Ground Waters. The following minimum criteria are applicable to all Class I and Class II ground waters:

Parameter	Criteria
(a) Pathogenic Organisms	Shall not be in amounts sufficient to render the ground waters detrimental to public health and welfare or impair the ground water for use as source of potable water.
(b) Coliform Bacteria	Shall not exceed the maximum contaminant level as stated in the National Interim Primary Drinking Water Standards.
(c) Arsenic	Shall not exceed 0.05 mg/l
(d) Barium	Shall not exceed 1.0 mg/l
(e) Cadmium	Shall not exceed 0.01 mg/l
(f) Chromium	Shall not exceed 0.05 mg/l
(g) Copper	Shall not exceed 1.0 mg/l
(h) Fluoride	Shall not exceed 2.4 mg/l
(i) Foaming Agents	Shall not exceed 0.5 mg/l
(j) Iron	Shall not exceed 0.3 mg/l
(k) Lead	Shall not exceed 0.05 mg/l
(l) Manganese	Shall not exceed 0.05 mg/l
(m) Mercury	Shall not exceed 0.002 mg/l
(n) Nitrate Nitrogen (as Nitrogen)	Shall not exceed 10.0 mg/l
(o) Total Trihalomethanes	Shall not exceed 0.1 mg/l
(p) Selenium	Shall not exceed 0.01 mg/l
(q) Silver	Shall not exceed 0.05 mg/l
(r) Sulfate	Shall not exceed 250 mg/l
(s) Zinc	Shall not exceed 5.0 mg/l
(t) Endrin (1,2,3,4,10, 10-hexachloro-1,7-epoxy-1, 4,4a,5,6,7,8,9a-octahydro-1,4-endo-5,8-dimethanonaphthalene)	Shall not exceed 0.0002 mg/l
(u) Lindane (1,2,3,4,5, 6-hexachlorocyclohexane, gamma isomer)	Shall not exceed 0.004 mg/l
(v) Methoxychlor (1,1,1-Trichloro-2, 2-bis (p-methoxyphenyl) ethane)	Shall not exceed 0.1 mg/l

Table I (continued)

Parameter	Criteria
(w) Toxaphene ($C_{10}H_{10}Cl_8$, Technical Chlorinated Camphene, 67-69 percent chlorine)	Shall not exceed 0.005 mg/l
(x) Chlorophenoxys:	
2,4-D,(2,4-Dichlorophenoxyacetic acid)	Shall not exceed 0.1 mg/l
2,4,5-TP Silvex (2,4,5-Trichlorophenoxypropionic acid)	Shall not exceed 0.01 mg/l
(y) Radioactivity	Shall not exceed the maximum radionuclide contaminant levels as stated in the National Interim Primary Drinking Water Standards.
(z) pH	Shall be in the range of 6.5-8.5 standard units or not more than 0.2 units outside of the naturally occurring range.
(aa) All Other	None in such concentrations which in the opinion of the Director would impair the waters for use as a source of potable water or to cause or contribute to a condition in contravention of standards for other classified waters of the Commonwealth

(2) Class III Ground Waters. The following minimum criteria are applicable to all Class III ground waters:

Parameter	Criteria
(a) Pathogenic Organisms	Shall not be in amounts sufficient to render the ground waters detrimental to public health, safety or welfare.
(b) Radioactivity	Shall not exceed the maximum radionuclide contaminant levels as stated in the National Interim Primary Drinking Water Standards.

Table I (continued)

Parameters	Criteria
(c) All Other Pollutants	None in concentrations or combinations which upon exposure to humans will cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions or physical deformations or cause any significant adverse effects to the environment, or which would exceed the recommended limits on the most sensitive ground water use.

TABLE II - GROUNDWATER STANDARDS
per 314 CMR 6.07

SUBSTANCE	GROUNDWATER STANDARD (mg/l)
ACETONE	0.700
ALACHLOR	0.002
ALDICARB	0.010
ATRAZINE	0.001
BENZENE	0.005
BIS-(2-ETHYLHEXYL)-PHTHALATE	0.010
BROMOMETHANE	0.010
CARBOFURAN	0.010
CARBON TETRACHLORIDE	0.005
2,4-D	0.100
1,2-DIBROMO-3-CHLOROPROPANE	0.0002
o-DICHLOROBENZENE	0.600
p-DICHLOROBENZENE	0.005
1,2-DICHLOROETHANE	0.005
1,1-DICHLOROETHYLENE	0.007
DICHLOROMETHANE	0.005
1,2-DICHLOROPROPANE	0.001
1,3-DICHLOROPROPENE	0.002
DINOSEB	0.005
1,4-DIOXANE	0.050
ETHYLBENZENE	0.700
ETHYLENE DIBROMIDE	0.00004
ETHYLENE GLYCOL	5.500
METHYL ETHYL KETONE	0.350
METHYL ISOBUTYL KETONE	0.350
METHYL tertiary BUTYL ETHER	0.050
METOLACHLOR	0.008
OXAMYL	0.050
SODIUM	20.00
STYRENE	0.005
TETRACHLOROETHYLENE	0.005
TOLUENE	2.000

TABLE II - GROUNDWATER STANDARDS
per 314 CMR 6.07

Continued...

SUBSTANCE	GROUNDWATER STANDARD (mg/l)
1,1,1-TRICHLOROETHANE	0.200
TRICHLOROETHYLENE	0.005
TURBIDITY	1 Turbidity unit
XYLENE	1.000
VINYL CHLORIDE	0.002
RADIUM (226 + 228)	5 pCi/LITER
RADON	10,000 pCi/LITER
URANIUM	10 pCi/LITER
GROSS ALPHA PARTICLE ACTIVITY (excluding U & Rn)	15 pCi/LITER
BETA PARTICLE & PHOTONS	annual dose < 4 mrem/yr

DEQE REGULATIONS
Title 310, Code of Massachusetts Regulations

Part or Section Number	Title
6.00	Ambient Air Quality Standards for the Commonwealth of Massachusetts
7.00	Air Pollution Control
8.00	Prevention And/Or Abatement of Air Pollution Incident Emergencies
9.00	Administration of Waterways Licenses
10.00	Wetlands Protection
15.00	Minimum Requirements for the Subsurface Disposal of Sanitary Sewage
18.00	Installation, Operation and Maintenance of Solid Waste Transfer Stations
19.00	Disposal of Solid Waste by Sanitary Landfill
22.00	Drinking Water Regulations
23.00	Sanitary Protection of Waters Used by the Metropolitan District Commission for the Water Supply of any Town or Water Company Under the Authority of M.G.L. c. 92, s.17
27.00	Underground Water Source Protection
30.00	Hazardous Waste Regulations
32.00	Land Application of Sludge and Septage

DEQE REGULATIONS
Title 314, Code of Massachusetts Regulations

Part or Section Number	Title
2.00	Permit Procedures
3.00	Surface Water Discharge Permit Program
4.00	Surface Water Quality Standards
5.00	Ground Water Discharge Permit Program
6.00	Ground Water Quality Standards
7.00	Sewer System Extension and Connection Permit Program
8.00	Supplemental Requirements for Hazardous Waste Management Facilities
9.00	Certification for Dredging, Dredged Material Disposal and Filling in Waters
12.00	Operation and Maintenance and Pretreatment Standards for Wastewater Treatment Works and Indirect Dischargers
15.00	Rules for the Prevention and Control of Oil Pollution in the Waters of the Commonwealth

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH REGULATIONS
Title 105, Code of Massachusetts Regulations

Part or Section Number	Title
120.000	Control of Radiation Hazards of Radioactive Material and Machines which Emit Ionizing Radiation
200.000	Physical Examination of School Children
260.000	Prohibition Against Certain Fishing in New Bedford Harbor
410.000	Minimum Standards of Fitness for Human Habitation
420.000	Housing and Sanitation Standards for Farm Labor Camps
430.000	Sanitary Standards for Recreational Camps for Children
440.000	Minimum Standards for Developed Family Type Camp Grounds
445.000	Minimum Standards for Bathing Beaches
450.000	Minimum Health and Sanitation Standards and Inspection Procedures for Correctional Facilities and Detention Centers
460.000	Lead Poisoning Prevention and Control
510.000	Standards of Identity and Definitions of Purity and Quality of Food
515.000	Action Levels for Poisonous or Deleterious Substances in Food
610.000	Benzol, Carbon Tetrachloride and Other Substances Hazardous to Health
650.000	Hazardous Substances
651.000	Program for Air Testing and Remedial Measures for Residential Dwellings Insulated with Urea Formaldehyde Foam Insulation (UFFI)

MASSACHUSETTS DEPARTMENT OF LABOR & INDUSTRIES
REGULATIONS
Title 453, Code of Massachusetts Regulations

Part or Section Number	Title
4.00	Ionizing Radiation
6.00	The Removal, Containment, or Encapsulation of Asbestos

MASSACHUSETTS DEPARTMENT OF LABOR & INDUSTRIES
REGULATIONS
Title 454, Code of Massachusetts Regulations

Part or Section Number	Title
3.00	Ionizing Radiation
§10.05	Construction Industry Rules and Regulations - Medical Services and First Aid
§10.06	Construction Industry Rules and Regulations - Sanitation
§10.07	Construction Industry Rules and Regulations - Occupational Noise Exposure
§10.08	Construction Industry Rules and Regulations - Ionizing Radiation
§10.09	Construction Industry Rules and Regulations - Nonionizing Radiation
§10.10	Construction Industry Rules and Regulations - Gases, Vapors, Fumes, Dusts, and Mists
§10.11	Construction Industry Rules and Regulations - Illumination
§10.12	Construction Industry Rules and Regulations - Ventilation
§11.07	Structural Painting Safety Code - Health Requirements for Confined & Unconfined Work Spaces

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part or Section Number	Title
Part 50	National Primary and Secondary Ambient Air Quality Standards
Part 51	Requirements for Preparation, Adoption, and Submittal of Implementation Plans
Part 53	Ambient Air Monitoring Reference and Equivalent Methods
Part 58	Ambient Air Quality Surveillance
Part 60	Standards of Performance for New Stationary Sources
Part 61	National Emission Standards for Hazardous Air Pollutants
§80.20	Regulation of Fuels and Fuel Additives - Controls Applicable to Gasoline Distributors
Part 122	EPA Administered Permit Programs: The National Pollutant Discharge Elimination System
Part 125	Criteria and Standards for the National Pollutant Discharge Elimination System
Part 129	Toxic Pollutant Effluent Standards
Part 133	Secondary Treatment Regulation
Part 136	Guidelines Establishing Test Procedures for the Analysis of Pollutants
Part 141	National Primary Drinking Water Regulations
Part 143	National Secondary Drinking Water Regulations
Part 144	Underground Injection Control Program
Part 146	Underground Injection Control Program: Criteria and Standards

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part or Section Number	Title
§153.69	FIFRA Reporting Requirements for Risk Benefit Information - Completed Toxicological Studies
§153.70	FIFRA Reporting Requirements for Risk Benefit Information - Incomplete Toxicological Studies
§153.71	FIFRA Reporting Requirements for Risk Benefit Information - Epidemiological Studies
§153.72	FIFRA Reporting Requirements for Risk Benefit Information - Efficacy Studies
§153.73	FIFRA Reporting Requirements for Risk Benefit Information - Studies of Dietary or Environmental Pesticide Residues
§153.74	FIFRA Reporting Requirements for Risk Benefit Information - Incident Reports: General Policy
§153.75	FIFRA Reporting Requirements for Risk Benefit Information - Toxic or Adverse Effect Incident Reports
§153.76	FIFRA Reporting Requirements for Risk Benefit Information - Failure of Performance Incident Reports
§153.77	FIFRA Reporting Requirements for Risk Benefit Information - Dietary or Environmental Pesticide Residue Incident Reports
§153.78	FIFRA Reporting Requirements for Risk Benefit Information - Reporting of Other Information
§154.7	FIFRA Special Review Procedures - Criteria for Initiation ofSpecial Review
Part 158	Data Requirements for Registration
Part 160	Good Laboratory Practice Standards

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part or Section Number	Title
§162.11	Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act - Criteria for Determinations of Unreasonable Adverse Effects
Part 165	Regulations for the Acceptance of Certain Pesticides and Recommended Procedures for the Disposal and Storage of Pesticides and Pesticide Containers
Part 170	Worker Protection Standards for Agricultural Pesticides
Part 172	Experimental Use Permits
Part 180	Tolerances and Exemptions from Tolerances for Pesticide Chemicals In or On Raw Agricultural Commodities
Part 190	Environmental Radiation Protection Standards for Nuclear Power Operations
Part 191	Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes
Part 192	Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings
Part 201	Noise Emission Standards for Transportation Equipment; Interstate Rail Carriers
Part 202	Motor Carriers Engaged in Interstate Commerce
Part 204	Noise Emission Standards for Construction Equipment
Part 221	Applications for Ocean Dumping Permits under Section 102 of the Act

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part or Section Number	Title
Part 227	Criteria for the Evaluation of Permit Applications for Ocean Dumping of Materials
Part 228	Criteria for the Management of Disposal Sites for Ocean Dumping
Part 230	Section 404(b)(1) Guidelines for Specification of Disposal Sites for Dredged or Fill Material
Part 240	Guidelines for the Thermal Processing of Solid Wastes
Part 241	Guidelines for the Land Disposal of Solid Wastes
Part 243	Guidelines for the Storage and Collection of Residential, Commerical, and Institutional Solid Waste
Part 257	Criteria for Classification of Solid Waste Disposal Facilities and Practices
Part 260	Hazardous Waste Management System: General
Part 261	Identification and Listing of Hazardous Waste
Part 262	Standards Applicable to Generators of Hazardous Waste
Part 263	Standards Applicable to Transporters of Hazardous Waste
Part 264	Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
Part 265	Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
Part 266	Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part or Section Number	Title
Part 267	Interim Standards for Owners and Operators of New Hazardous Waste Land Disposal Facilities
Part 268	Land Disposal Restrictions
Part 270, Subpart B	EPA Administered Permit Programs: The Hazardous Waste Permit Program - Permit Application
Part 280	Underground Storage Tanks
Part 300	National Oil and Hazardous Substances Pollution Contingency Plan
Part 355	Emergency Planning and Notification
Part 401	General Provisions
Part 403	General Pretreatment Regulations for Existing and New Sources of Pollution
Part 405	Effluent Limitations Guidelines for Standards of Performance and Pretreatment Standards for New Sources for the Dairy Products Processing Industry Point Source Category
Part 406	Grain Mills Point Source Category
Part 407	Canned and Preserved Fruits and Vegetables Processing Point Source Category
Part 408	Canned and Preserved Seafood Processing Point Source Category
Part 409	Sugar Processing Point Source Category
Part 410	Textile Mills Point Source Category
Part 411	Cement Manufacturing Point Source Category

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part or Section Number	Title
Part 412	Feedlots Point Source Category
Part 413	Electroplating Point Source Category
Part 414	Organic Chemicals Manufacturing Point Source Category
Part 415	Inorganic Chemicals Manufacturing Point Source Category
Part 416	Plastics and Synthetics Point Source Category
Part 417	Soap and Detergent Manufacturing Point Source Category
Part 418	Fertilizer Manufacturing Point Source Category
Part 419	Petroleum Refining Point Source Category
Part 420	Iron and Steel Manufacturing Point Source Category
Part 421	Nonferrous Metals Manufacturing Point Source Category
Part 422	Phosphate Manufacturing Point Source Category
Part 423	Steam Electric Power Generating Point Source Category
Part 424	Ferroalloy Manufacturing Point Source Category
Part 425	Leather Tanning and Finishing Point Source Category
Part 426	Glass Manufacturing Point Source Category
Part 427	Asbestos Manufacturing Point Source Category

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part or Section Number	Title
Part 428	Rubber Manufacturing Point Source Category
Part 429	Timber Products Processing Point Source Category
Part 430	Pulp, Paper, and Paperboard Point Source Category
Part 431	The Builders Paper and Board Mills Point Source Category
Part 432	Meat Products Point Source Category
Part 433	Metal Finishing Point Source Category
Part 434	Coal Mining Point Source Category; BPT, BAT, BCT Limitations and New Source Performance Standards
Part 435	Oil and Gas Extraction Point Source Category
Part 436	Mineral Mining and Processing Point Source Category
Part 439	Pharmaceutical Manufacturing Point Source Category
Part 440	Ore Mining and Dressing Point Source Category
Part 443	Effluent Limitations Guidelines for Existing Sources and Standards of Performance and Pretreatment Standards for New Sources for the Paving and Roofing Materials (Tars and Asphalt) Point Source Category
Part 446	Paint Formulating Point Source Category
Part 447	Ink Formulating Point Source Category
Part 454	Gum and Wood Chemicals Manufacturing Point Source Category
Part 455	Pesticide Chemicals

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part of Section Number	Title
Part 457	Explosives Manufacturing Point Source Category
Part 458	Carbon Black Manufacturing Point Source Category
Part 459	Photographic Point Source Category
Part 460	Hospital Point Source Category
Part 461	Battery Manufacturing Point Source Category
Part 463	Plastics Molding and Forming Point Source Category
Part 464	Metal Molding and Casting Point Source Category
Part 465	Coil Coating Point Source Category
Part 466	Porcelain Enameling Point Source Category
Part 467	Aluminum Forming Point Source Category
Part 468	Copper Forming Point Source Category
Part 469	Electrical and Electronic Components Point Source Category
Part 471	Nonferrous Metals Forming and Metal Powders Point Source Category
Part 716	Health and Safety Data Reporting
Part 717	Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment
Part 747	Metalworking Fluids
Part 761	Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions

EPA REGULATIONS
Title 40, Code of Federal Regulations

Part of Section Number	Title
Part 762	Fully Halogenated Chlorofluoroalkanes
Part 763	Asbestos
Part 766	Dibenzo-para-dioxins/Dibenzofurans
Part 792	Good Laboratory Practice Standards
Part 795	Provisional Test Guidelines
Part 796	Chemical Fate Testing Guidelines
Part 797	Environmental Effects Testing Guidelines
Part 798	Health Effects Testing Guidelines
Part 799	Identification of Specific Chemical Substance and Mixture Testing Requirements

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION REGULATIONS
Title 29, Code of Federal Regulations

Part or Section Number	Title
§1910.1000	Occupational Safety and Health Standards - Air Contaminants
§1910.1001	Occupational Safety and Health Standards - Asbestos, Tremolite, Anthophyllite and Actinolite
§1910.1002	Occupational Safety and Health Standards - Coal Tar Pitch Volatiles; Interpretation of Term
§1910.1003	Occupational Safety and Health Standards - 4-Nitrobiphenyl
§1910.1004	Occupational Safety and Health Standards - Alpha-Naphthylamine
§1910.1006	Occupational Safety and Health Standards - Methyl Chloromethyl Ether
§1910.1007	Occupational Safety and Health Standards - 3,3--Dichlorobenzidine (and its salts)
§1910.1008	Occupational Safety and Health Standards - Bis-Chloromethyl Ether
§1910.1009	Occupational Safety and Health Standards - Beta-Naphthylamine
§1910.1010	Occupational Safety and Health Standards - Benzidine
§1910.1011	Occupational Safety and Health Standards - 4-Aminodiphenyl
§1910.1012	Occupational Safety and Health Standards - Ethyleneimine
§1910.1013	Occupational Safety and Health Standards - Beta-Propiolactone
§1910.1014	Occupational Safety and Health Standards - 2-Acetylaminofluorene
§1910.1015	Occupational Safety and Health Standards - 4-Dimethylaminoazobenzene

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION REGULATIONS
Title 29, Code of Federal Regulations

Part or Section Number	Title
§1910.1016	Occupational Safety and Health Standards - N-Nitrosodimethylamine
§1910.1017	Occupational Safety and Health Standards - Vinyl Chloride
§1910.1018	Occupational Safety and Health Standards - Inorganic Arsenics
§1910.1025	Occupational Safety and Health Standards - Lead
§1910.1029	Occupational Safety and Health Standards - Coke Oven Emissions
§1910.1043	Occupational Safety and Health Standards - Cotton Dust
§1910.1044	Occupational Safety and Health Standards - 1,2-Dibromo-3-Chloropropane
§1910.1045	Occupational Safety and Health Standards - Acrylonitrile
§1910.1047	Occupational Safety and Health Standards - Ethylene Oxide

OTHER FEDERAL AGENCIES

Name of Agency	Code of Federal Regulations Title Number	Part or Section	Title of Regulation Number
Department of Health and Human Services, Food & Drug Administration	21	§103.35	Quality Standards for Foods with No Identity Standards - Bottled Water
		Part 189	Substances Prohibited from Use in Human Food
		Part 190	Tolerances for Pesticides in Food Administered by the Environmental Protection Agency
		Part 561	Tolerances for Pesticides in Animal Feeds Administered by the Environmental Protection Agency
		Part 589	Substances Prohibited from Use in Animal Food or Feed
		Part 700, Subpart B	Requirements for Specific Cosmetic Products

OTHER FEDERAL AGENCIES

Name of Agency	Code of Federal Regulations Title Number	Part or Section	Title of Regulation Number
Department of Transportation, Coast Guard	33	Part 126	Handling of Explosives or Other Dangerous Cargoes Within or Contiguous to Waterfront Facilities
		§153.305	Methods and Procedures for the Removal of Discharged Oil
		Part 154	Oil Pollution Prevention Regulations for Marine Oil Transfer Facilities
		§156.125	Oil Discharge Cleanup
		§156.130	Connection
		§156.160	Supervision by Person in Charge
		§156.170	Equipment Tests and Inspections
		Part 157	Rules for the Protection of the Marine Environment Relating to Tank Vessels Carrying Oil in Bulk

OTHER FEDERAL AGENCIES

Name of Agency	Code of Federal Regulations Title Number	Part or Section	Title of Regulation Number
Department of Transportation, Coast Guard	33	Part 158	Control of Residues and Mixtures Containing Oil or Noxious Liquid Substances
		Part 159	Marine Sanitation Devices
Department of Agriculture, Forest Service	36	Part 261	Prohibitions
Department of the Interior, National Park Service	37	§7.100	Special Regulations, Areas of the National Park System- Appalachian National Scenic Trail
		Part 27	Cape Cod National Seashore; Zoning Standards
Department of Health and Human Services, Public Health Service	42	Part 85	Requests for Health Hazard Evaluations
	42	Part 85a	Occupational Safety and Health Investigations of Places of Employment

OTHER FEDERAL AGENCIES

Name of Agency	Code of Federal Regulations Title Number	Part or Section	Title of Regulation Number
Department of the Interior, Fish and Wildlife Service	50	Part 17	Endangered and Threatened Wildlife and Plants

APPENDIX D

POTENTIALLY APPLICABLE OR SUITABLY ANALOGOUS "GUIDELINES"

Appendix D-1

Potentially Applicable or Suitably Analogous

PUBLIC HEALTH GUIDELINES

(Guidelines are for use in method 3a only)

AMBIENT AIR

Substance	ORS Guideline
Dioxin (Total dibenzofurans and dibenzodioxins)	1.1 picogram/m^3

Allowable Ambient Limits (AALs)
(see following tables)

Massachusetts
Allowable Ambient Limits (AALs) For AIR

** Concentrations expressed as annual averages **

CHEMICAL	CAS NUMBER	ALLOWABLE AMBIENT LIMIT (AAL) ug/m3	ppb
ACETALDEHYDE	75070	0.44	0.18
ACETONE	67641	160.54	68.03
ACRYLONITRILE	107131	0.01	0.01
ALKANES/ALKENES (not to exceed 25% n-hexane)		47.62	-
AMMONIA	7664417	4.73	6.80
ANILINE	62533	0.14	0.04
ASBESTOS	1332214	0.0001	f/cm3
BENZENE	71432	0.12	0.04
BENZYL CHLORIDE	100447	0.94	0.18
BERYLLIUM	7440417	0.0004	-
1,3-BUTADIENE	106990	0.003	0.002
n-BUTYL ALCOHOL	71363	412.24	136.05
CADMIUM	7440439	0.001	-
CALCIUM CHROMATE	13765190	0.0001	-
CARBON DISULFIDE	75150	0.27	0.82
CARBON TETRACHLORIDE	56235	0.07	0.01
CHLORDANE	57749	0.03	0.002
CHLORINE	7782505	3.95	1.36
CHLOROBENZENE	108907	6.26	1.36
CHLOROETHANE	75003	358.78	136.05
CHLOROFORM	67663	0.04	0.01
CHLOROPRENE	126998	0.98	0.27
CHROMIC ACID	13765190	0.0001	-
CHROMIUM(METAL)	7440473	0.68	-
CHROMIUM (VI) COMPOUNDS		0.0001	-
COPPER	7440508	0.54	-
p-CRESOL	106445	12.02	2.72
CYCLOHEXANE	110827	280.82	81.63
o-DICHLOROBENZENE	95501	81.74	13.61
p-DICHLOROBENZENE	106467	0.18	0.03
1,2-DICHLOROETHANE	107062	0.04	0.01
1,2-DICHLOROETHYLENE	540590	107.81	27.21
DICHLOROMETHANE	75092	0.24	0.07
1,2-DICHLOROPROPANE	78875	0.05	0.01
DIETHYLAMINE	109897	4.07	1.36
DI(2-ETHYLHEXYL)-PHTHALATE	117817	0.77	0.05
DIMETHYLFORMAMIDE	68122	8.13	2.72
1,4-DIOXANE	123911	0.24	0.07
DIPHENYL	92524	0.09	0.01

CHEMICAL	CAS NUMBER	ALLOWABLE AMBIENT LIMIT (AAL) ug/m3	ppb
DIPHENYLAMINE	122394	0.68	0.10
EPICHLOROHYDRIN	106898	0.54	0.14
ETHANOL	64175	51.24	27.21
ETHYL ACETATE	141786	391.84	108.84
ETHYL ACRYLATE	140885	0.28	0.07
ETHYLBENZENE	100414	118.04	27.21
ETHYLENE GLYCOL	107211	34.50	13.61
ETHYL ETHER	60297	164.90	54.42
FLUORIDE	16984488	6.80	8.76
FORMALDEHYDE	50000	0.08	0.06
FURAN	110009	0.02	0.007
HEPTACHLOR	76448	0.001	0.0001
HEXACHLOROCYCLO-PENTADIENE	77474	0.006	0.0005
HEXACHLOROETHANE	67721	0.25	0.03
HEXACHLOROPHENE	70304	-	-
2-HEXANONE	591786	10.88	2.66
HYDRAZINE	302012	0.002	0.001
HYDROGEN CHLORIDE	7647010	2.03	1.36
HYDROGEN FLUORIDE	7664393	0.34	0.42
HYDROGEN SULFIDE	7783064	3.79	2.72
ISOAMYL ACETATE	123922	144.76	27.21,
ISOBUTYL ACETATE	110190	193.77	40.82
ISOBUTYL ALCOHOL	78831	41.22	13.61
ISOPROPYL ACETATE	108214	283.81	68.03
LEAD	7439921	0.07	-
LEAD SUBACETATE	1335326	0.01	-
LINDANE	58899	0.003	0.0002
MALEIC ANHYDRIDE	108316	0.14	0.03
METHANOL	67561	7.13	5.44
2-METHOXY ETHANOL	109864	2.12	0.68
METHYL ACRYLATE	96333	4.79	1.36
METHYL BROMIDE	74839	2.64	0.68
METHYL ETHYL KETONE (MEK)	78933	32.07	10.88
METHYL ISOBUTYL KETONE (MIBK)	108101	55.70	13.61
METHYL MERCURY	7439976	0.0014	-
METHYL METHACRYLATE	80626	22.27	5.44
MIREX	2385855	-	-
NAPTHALENE (including 2-methylnaphthalene)	91203	14.25	2.72
NICKEL (METAL)	7440020	0.18	-
NICKEL OXIDE	1313991	0.01	-
NITROBENZENE	98953	6.84	1.36

CHEMICAL	CAS NUMBER	ALLOWABLE AMBIENT LIMIT (AAL) ug/m3	ppb
PENTACHLOROPHENOL	87865	0.01	0.001
PHENOL	108952	52.33	13.61
PHOSPHORIC ACID	7664382	0.27	0.07
PHTHALIC ANHYDRIDE	85449	0.82	0.14
PCBs	1336363	0.0005	-
PROPYL ALCOHOL	71238	133.63	54.42
PROPYLENE OXIDE	75569	1.50	0.63
RESORCINOL	108463	3.06	0.68
SELENIUM	7782492	0.54	-
SELENIUM SULFIDE	7446346	0.05	-
STYRENE	100425	1.75	0.41
SULFURIC ACID	7664939	2.72	0.68
1,1,2,2-TETRACHLORO-1,2-DIFLUOROETHANE	76120	566.67	68.03
1,1,2,2-TETRACHLOROETHANE	79345	0.02	0.003
TETRACHLOROETHYLENE	127184	0.02	0.003
TETRAHYDROFURAN	109999	80.18	27.21
TOLUENE	108883	10.24	2.72
TOLUENE DIISOCYANATE	584849	0.10	0.01
o-TOLUIDINE	95534	0.17	0.04
1,1,1-TRICHLOROETHANE	71556	1038.37	190.48
1,1,2-TRICHLOROETHANE	79005	0.06	0.01
TRICHLOROETHYLENE	79016	0.61	0.11
2,4,6-TRICHLOROPHENOL	95954	0.16	-
TRIETHYLAMINE	121448	1.13	0.27
VANADIUM	1314621	0.27	-
VANADIUM PENTOXIDE	1314621	0.03	0.005
VINYL ACETATE	108054	9.57	2.72
VINYL CHLORIDE	75014	0.38	0.15
VINYLIDENE CHLORIDE	75354	0.02	0.01
XYLENES (m-,o-,p-,ISOMERS)	1330207	11.80	2.72

Massachusetts
Allowable Ambient Limits - 24 Hour
Threshold Effects Exposure Limit (TEL)

CHEMICAL	CAS NUMBER	THRESHOLD EFFECTS EXPOSURE LIMIT (TEL) ** 24 hour ** ug/m3	ppb
ACETALDEHYDE	75070	4.89	2.72
ACETONE	67641	160.54	68.03
ACRYLONITRILE	107131	1.18	0.54
ALKANES/ALKENES (not to exceed 25% n-hexane)		95.24	-
AMMONIA	7664417	4.73	6.80
ANILINE	62533	2.07	0.54
ASBESTOS	1332214	0.0002f/cm3	
BENZENE	71432	1.74	0.54
BENZYL CHLORIDE	100447	14.08	2.72
BERYLLIUM	7440417	0.001	-
1,3-BUTADIENE	106990	1.20	0.54
n-BUTYL ALCOHOL	71363	412.24	136.05
CADMIUM	7440439	0.003	-
CALCIUM CHROMATE	13765190	0.003	-
CARBON DISULFIDE	75150	0.27	0.82
CARBON TETRACHLORIDE	56235	85.52	13.61
CHLORDANE	57749	0.14	0.008
CHLORINE	7782505	3.95	1.36
CHLOROBENZENE	108907	93.88	20.41
CHLOROETHANE	75003	717.55	272.11
CHLOROFORM	67663	132.76	27.21
CHLOROPRENE	126998	0.98	0.27
CHROMIC ACID	7738945	0.003	-
CHROMIUM(METAL)	7440473	1.36	-
CHROMIUM (VI) COMPOUNDS		0.003	-
COPPER	7440508	0.54	-
p-CRESOL	106445	24.05	5.44
CYCLOHEXANE	110827	280.82	81.63
o-DICHLOROBENZENE	95501	81.74	13.61
p-DICHLOROBENZENE	106467	122.61	20.41
1,2-DICHLOROETHANE	107062	11.01	2.72
1,2-DICHLOROETHYLENE	540590	215.62	54.42
DICHLOROMETHANE	75092	9.45	2.72
1,2-DICHLOROPROPANE	78875	94.23	20.41
DIETHYLAMINE	109897	8.13	2.72
DI(2-ETHYLHEXYL)-PHTHALATE	117817	1.36	0.09
DIMETHYLFORMAMIDE	68122	8.13	2.72
1,4-DIOXANE	123911	24.49	6.80
DIPHENYL	92524	0.34	0.05

CHEMICAL	CAS NUMBER	THRESHOLD EFFECTS EXPOSURE LIMIT (TEL) ** 24 hour ** ug/m3	ppb
DIPHENYLAMINE	122394	2.72	0.39
EPICHLOROHYDRIN	106898	0.54	0.14
ETHANOL	64175	51.24	27.21
ETHYL ACETATE	141786	391.84	108.84
ETHYL ACRYLATE	140885	0.56	0.14
ETHYLBENZENE	100414	118.04	27.21
ETHYLENE GLYCOL	107211	34.50	13.61
ETHYL ETHER	60297	329.80	108.84
FLUORIDE	16984488	6.80	8.76
FORMALDEHYDE	50000	0.33	0.27
FURAN	110009	0.40	0.14
HEPTACHLOR	76448	0.14	0.009
HEXACHLOROCYCLO-PENTADIENE	77474	0.006	0.0005
HEXACHLOROETHANE	67721	0.53	0.05
HEXACHLOROPHENE	70304	-	-
2-HEXANONE	591786	10.88	2.66
HYDRAZINE	302012	0.007	0.005
HYDROGEN CHLORIDE	7647010	2.03	1.36
HYDROGEN FLUORIDE	7664393	0.68	0.83
HYDROGEN SULFIDE	7783064	3.79	2.72
ISOAMYL ACETATE	123922	144.76	27.21
ISOBUTYL ACETATE	110190	193.77	40.82
ISOBUTYL ALCOHOL	78831	41.22	13.61
ISOPROPYL ACETATE	108214	283.81	68.03
LEAD	7439921	0.14	-
LEAD SUBACETATE	1335326	0.14	-
LINDANE	58899	0.14	0.11
MALEIC ANHYDRIDE	108316	0.27	0.07
METHANOL	67561	7.13	5.44
2-METHOXY ETHANOL	109864	4.23	1.36
METHYL ACRYLATE	96333	9.57	2.72
METHYL BROMIDE	74839	5.28	1.36
METHYL ETHYL KETONE (MEK)	78933	32.07	10.88
METHYL ISOBUTYL KETONE (MIBK)	108101	55.70	13.61
METHYL MERCURY	7439976	0.003	-
METHYL METHACRYLATE	80626	22.27	5.44
MIREX	2385855	-	-
NAPHTHALENE (including 2-methylnaphthalene)	91203	14.25	2.72
NICKEL (METAL)	7440020	0.27	-
NICKEL OXIDE	1313991	0.27	-
NITROBENZENE	98953	13.69	2.72

24-Hour AALs : TELs, continued...

CHEMICAL	CAS NUMBER	THRESHOLD EFFECTS EXPOSURE LIMIT (TEL) ** 24 hour ** ug/m3	ppb
PENTACHLOROPHENOL	87865	0.01	0.001
PHENOL	108952	52.33	13.61
PHOSPHORIC ACID	7664382	0.27	0.07
PHTHALIC ANHYDRIDE	85449	1.65	0.27
PCBs	1336363	0.003	-
PROPYL ALCOHOL	71238	133.63	54.42
PROPYLENE OXIDE	75569	12.92	5.44
RESORCINOL	108463	12.24	2.72
SELENIUM	7782492	0.54	-
SELENIUM SULFIDE	7446346	0.54	-
STYRENE	100425	115.81	27.21
SULFURIC ACID	7664939	2.72	0.68
1,1,2,2-TETRACHLORO-1,2-DIFLUOROETHANE	76120	1133.33	136.05
1,1,2,2-TETRACHLORO-ETHANE	79345	18.67	2.72
TETRACHLOROETHYLENE	127184	922.18	136.05
TETRAHYDROFURAN	109999	160.35	54.42
TOLUENE	108883	10.24	2.72
TOLUENE DIISOCYANATE	584849	0.10	0.01
o-TOLUIDINE	95534	2.38	0.54
1,1,1-TRICHLORO-ETHANE	71556	1038.37	190.48
1,1,2-TRICHLORO-ETHANE	79005	14.84	2.72
TRICHLOROETHYLENE	79016	36.52	6.80
2,4,6-TRICHLORO-PHENOL	88062	-	-
TRIETHYLAMINE	121448	1.13	0.27
VANADIUM	1314621	0.27	-
VANADIUM PENTOXIDE	1314621	0.14	0.02
VINYL ACETATE	108054	38.29	10.88
VINYL CHLORIDE	75014	3.47	1.36
VINYLIDENE CHLORIDE	75354	1.08	0.27
XYLENES (m-,o-,p-,ISOMERS)	1330207	11.80	2.72

Potentially Applicable or Suitably Analogous

PUBLIC HEALTH GUIDELINES

(Guidelines are for use in method 3a. only)

DRINKING WATER

Substance	DEQE Guidelines (mg/Liter)
Acetone	0.700
Alachlor	0.002
Aldicarb	0.010
Atrazine	0.001
Bis-(2-Ethylhexyl)-Phthalate	0.010
Bromomethane	0.010
Carbofuran	0.010
Carbon Tetrachloride	0.005
1,2-Dibromo-3-Chloropropane	0.0002
o-Dichlorobenzene	0.600
p-Dichlorobenzene	0.005
Dichloromethane	0.005
1,2-Dichloropropane	0.001
1,3-Dichloropropene	0.002
Dinoseb	0.005
1,4-Dioxane	0.050
Ethylbenzene	0.700
Ethylene Dibromide	0.00004
Ethylene Glycol	5.5
Methyl Ethyl Ketone	0.350
Methyl Isobutyl Ketone	0.350
Methyl tertiary Butyl Ether	0.050
Metolachlor	0.008
Oxamyl	0.050
Styrene	0.005
Tetrachloroethylene	0.005
Toluene	2.000
Xylenes	1.0
Radon	10,000 pCi/Liter
Uranium	10 pCi/Liter

APPENDIX E

POTENTIALLY APPLICABLE OR SUITABLY ANALOGOUS "POLICIES"

APPENDIX E

Potentially Applicable or Suitably Analogous

PUBLIC HEALTH POLICIES and

ENVIRONMENTAL POLICIES

The following list represents only a partial collection of Department Policies. Each Division should be consulted for the most recent version of any policy. Copies may be available at each Division Office for a slight fee.

DIVISION of WATER SUPPLY

Number	Title
P86-01	Submission of Hydrogeological Reports by Hydrogeologists
P86-02	Procedure for New Groundwater Source Approvals
P86-03	Non-Municipal Water Quality Analysis
P87-04	Procedures for the Use of EPA's PMCLs
P87-09	Adoption of Water Supply Contamination Correction Policies WSCC-1 through WSCC-6
P87-12	Quality Assurance for Groundwater Monitoring
P87-20	The Determination and Management of the Protective Radius (Zone I) for Public Supply Wells
P87-25	Items to Consider When Conditioning New Source Approvals
P88-02	Review of Sewer Line/Water Supply Protection
P88-03	Interim Wellhead Protection Area

DIVISION of SOLID WASTE

Number	Title
SWM-1	Policy for the Handling and Disposal of "Non Friable" Asbestos Waste
SWM-2	Interim Oil Ash Disposal Policy
SWM-3	Coal Ash Landfill Cover and Disposal Policy
SWM-4-3/88	Policy for the Disposal of Urea Formaldehyde Foam Insulation (UFFI)
SWM-5	Policy on Tire Disposal and Stockpiling
SWM-6	Policy on the Disposal of Woodwastes
SWM-7-7/88	Ash Management and Disposal Policy
SWM-8-1/88	Leaf Composting Policy
SWM-9-7/88	Ash Sampling and Analysis Guidance

APPENDIX F

GLOSSARY OF TERMS AND ACRONYMS

Glossary of Terms and Acronyms

ADD	-	Average Daily Dose of a contaminant received by a receptor of concern (units of mg/kg/day)
ADD_a	-	Average Daily Dose, Acute
ADD_c	-	Average Daily Dose, Chronic
ADD_{dw}	-	Total Average Daily Dose received via drinking water exposures: $ADD_{dw} = ADD_{dwd} + ADD_{dwi} + ADD_{dwih}$
ADD_{dwd}	-	Average Daily Dose received via dermal absorption from contaminated drinking water
ADD_{dwi}	-	Average Daily Dose received via ingestion of contaminated drinking water
ADD_{dwih}	-	Average Daily Dose received via inhalation of contaminants volatilized from contaminated drinking water supplies
ADD_{fi}	-	Average Daily Dose received via ingestion of contaminated food
ADD_{inh}	-	Total Average Daily Dose via Inhalation $ADD_{inh} = ADD_{inhp} + ADD_{inhg}$
ADD_{inhp}	-	Average Daily Dose received via inhalation of particulates
ADD_{inhg}	-	Average Daily Dose received via inhalation of gaseous contaminants
ADD_{mm}	-	Average Daily Dose received from contaminated mother's milk
ADD_s	-	Average Daily Dose, Subchronic
ADD_{so}	-	Total Average Daily Dose received via direct contact with contaminated soil: $ADD_{so} = ADD_{sod} + ADD_{soi}$
ADD_{sod}	-	Average Daily Dose received via absorption during dermal contact with contaminated soil
ADD_{soi}	-	Average Daily Dose received via incidental ingestion of contaminated soil

ADD_{sw}	-	Total Average Daily Dose received via exposures to contaminated surface water: $ADD_{sw} = ADD_{swd} + ADD_{swi} + ADD_{swih}$
ADD_{swd}	-	Average Daily Dose received via dermal contact with contaminated surface water
ADD_{swi}	-	Average Daily Dose received via incidental ingestion of contaminated surface water
ADD_{swih}	-	Average Daily Dose received via inhalation of contaminants volatilized from surface water
AF	-	Fraction of OHM in soil absorbed through the skin (unitless)
AIC	-	Allowable Intake, Chronic
AIS	-	Allowable Intake, Subchronic
AP	-	Averaging Period (units: days)
Background	-	The level of oil or hazardous material in the environment which would exist in the absence of the disposal site
BAF	-	Bioavailability Adjustment Factor (unitless)
BW_{avg}	-	Average Body Weight of the receptor of concern during the period of exposure (units: mass)
C	-	Appropriate units conversion factor
D_1	-	Average duration of each exposure event (units: hours/event)
D_2	-	Duration of the exposure period (units: days)
DEQE	-	The Massachusetts Department of Environmental Quality Engineering
Disposal Site	-	Any structure, well, pit, pond, lagoon, impoundment, ditch, landfill or other place or area, excluding ambient air or surface water, where uncontrolled oil or hazardous material has come to be located as a result of any spilling, leaking, pouring, abandoning, emitting, emptying, discharging, injecting, escaping, leaching, dumping, discarding, or otherwise disposing of such oil or hazardous material. The

term shall not include any site containing only oil or hazardous materials which: are lead-based paint residues emanating from a point of original application of such paint; resulted from emissions from the exhaust of an engine; are building materials still serving their original intended use or emanating from such use; or resulted from release of source, by-product or special nuclear material from a nuclear incident, as those terms are defined in 42 U.S.C.s.2014, if such release was subject to requirements with respect to financial protection established by the Nuclear Regulatory Commission under 42 U.S.C.s.2210. A Disposal Site requires a Remedial Response Action.

Dose - The amount of a substance, expressed in mg/kg body weight/day, which is absorbed into the body as a result of exposure(s).

ELCR - Excess Lifetime Cancer Risk

Environment - Waters, land, surface or subsurface strata, or ambient air of the Commonwealth

EP - Exposure Point

EPA - The US Environmental Protection Agency

EPC - Exposure Point Concentration

Excess Lifetime Cancer Risk - The estimated probability that an individual's exposure, during a lifetime, to an oil or hazardousmaterial would result in cancer.

Exposure - Any contact with or ingestion, inhalation, or assimilation of oil or hazardous materials, including irradiation. Also, the amount of material contacted and available for absorption.

Exposure Point - The place at which a human or environmental receptor is exposed to an oil or hazardous material

Exposure Point Concentration - The concentration of an oil or hazardous material in a specific medium at an exposure point.

F - Average number of events/day during the period of exposure (units: events/day)

FI - Daily intake of contaminated food on days exposed during the exposure period (units: mass/event)

Hazard Index - A calculation of the possibility of non-cancer health effects as the result of exposure to one or more oil or hazardous materials with similar modes of toxic action. The Hazard Index (HI) is defined as $HI = D_1/AD_1 + D_2/AD_2 + \ldots D_i/AD_i$ where D is the daily dose for a particular oil or hazardous material, and AD is the allowable daily dose for a particular oil or hazardous material. The allowable daily dose is the Reference Dose or other allowable daily dose specified by the Department.

Hazardous Material - Material including, but not limited to, any material in whatever form which, because of its quantity, concentration, chemical, corrosive, flammable, reactive, toxic, infectious or radioactive characteristics, either separately or in combination with any substance or substances, constitutes a present or potential threat to human health, safety, welfare, or to the environment, when improperly stored, treated, transported, disposed of, used, or otherwise managed. The term shall not include oil, but shall include waste oil and all those substances which are included under 42 U.S.C.s.9601(14), but it is not limited to those substances. The term shall include but should not be limited to, all materials regulated as hazardous waste or regulated recyclable materials pursuant to 310 CMR 30.000.

HI - Hazard Index

I - Daily soil ingestion rate on days exposed during the exposure period (units: mass/day)

IARC - The International Agency for Research on Cancer

Imminent Hazard - A hazard which would pose a significant or otherwise unacceptable risk of harm to health, safety, public welfare or the environment if it were present for even a short period of time.

IRIS	-	The US EPA's Integrated Risk Information System
LADD	-	Lifetime Average Daily Dose
Limit of Detection	-	Generally, the smallest concentration of a substance that can be reliably distinguished from background noise. Typically, the signal to noise ration is 3.
LOD	-	Limit of Detection
Massachusetts-Contingency Plan		310 CMR 40.000
MCP	-	The Massachusetts Contingency Plan
MDL	-	Method Detection Limit
Media	-	Air, soil, or water.
Method Detection Limit	-	Generally, the level which can be measured with 99% accuracy using EPA Standard Methods.
Migration Pathway	-	A pathway by which an oil or hazardous material is transported at or from a disposal site.
MS	-	Mass of soil in contact with unit surface area of skin (units: mass/area)
NOAEL	-	The No Observable Adverse Effects Level
OHM	-	Oil or Hazardous Material
Oil	-	Insoluble or partially soluble oils of any kind or origin or in any form, including, without limitation, crude or fuel oils, lube oil or sludge, asphalt, insoluble or partially insoluble derivatives of mineral, animal or vegetable oils. The term shall not include waste oil, and shall not include those substances which are included in 42 U.S.C.s. 9601(14).

Permanent Solution	-	A measure or combination of measures which will, when implemented, ensure attainment of a level of control of each identified substance of concern at a disposal site or in the surrounding environment such that no substance of concern will present a significant or otherwise unacceptable risk of damage to health, safety, public welfare, or the environment during any foreseeable period of time.
Potency	-	US EPA's Cancer Assessment Group's published cancer slope value
Potentially Responsible Party	-	Any person who is potentially liable pursuant to MGL c. 21E (PRP)
PQL	-	Practical Quantitation Limit
Practical Quantitation Limit	-	Generally, the smallest concentration of a substance for which quantitative results may be obtained with a specified degree of confidence.
PRP	-	A Potentially Responsible Party
q_1^*		US EPA's Cancer Assessment Group's published cancer slope value
Receptors	-	Individual or environmental population exposed to oil or hazardous materials.
Reference Dose	-	The daily dose of an oil or hazardous material whichwould not be expected to result in any adverse non-cancer health effects as published by EPA.
Release	-	Includes any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping or disposing into the environment, but excludes: (1) emissions from the exhaust of an engine; (2) release of source, by-product, or special nuclear material from a nuclear incident, as those terms are defined in 42 U.S.C.s.2014, if such release is subject to requirements with respect to financial protection established by the Nuclear Regulatory Commission under 42 U.S.C.s 2210; (3) the normal application of fertilizer; and (4) the application of pesticides in a manner consistent with their labeling.

Remedial Response Action	-	A response action at a Location To Be Investigated (LTBI) or a disposal site that is taken pursuant tothe Massachusetts Contingency Plan
RfD	-	The US EPA's published Reference Dose
Route of Exposure	-	A mechanism, including, but not limited to ingestion, inhalation, dermal absorption, and transpiration by which an oil or hazardous material comes into contact with a human or environmental receptor.
RP	-	Respirable Particulates (units: mass)
SA	-	Skin surface area in contact with the contaminated soil on days exposed (units: area/day)
Site	-	Any building, structure, installation, equipment, pipe or pipeline including any pipe discharging into a sewer or publicly-owned treatment works, well, pit, pond, lagoon, impoundment, ditch, landfill, storage container, motor vehicle, rolling stock, or aircraft, or any other place or area where oil or hazardous material has been deposited, stored, disposed of or placed, or otherwise come to be located. The term shall not include any consumer product in consumer use or any vessel.
Substantial Hazard	-	A hazard which would pose a significant or otherwise unacceptable risk of harm to health, safety, public welfare, or the environment if it continued to be present for several years.
TEL	-	Threshold Effects Level (from CHEM, DEQE 1989)
Temporary Solution	-	A measure or combination of measures which will, when implemented, eliminate any substantial hazards posed by a priority disposal site until a permanent solution can be implemented.
Total Site Cancer Risk	-	The sum of the estimated excess lifetime cancer risks associated with exposure to all oil and hazardous materials at or from a disposal site at all exposure points for a given receptor.

Total Site Non-Cancer Risk	-	A calculation of the possibility of non-cancer health effects associated with exposure to all oil and hazardous materials at or from a disposal site at all exposure points for a given receptor. The Hazard Index is a measure of the Total Site Non-Cancer Risk.
UF	-	Uncertainty Factor
VI	-	Daily volume of drinking water ingested by the receptor of concern at the exposure point during the exposure period (units: volume/day)
VM	-	Daily volume of mother's milk ingested by the infant during the exposure period (units: volume/day)
VR	-	Daily respiratory volume for the receptor of concern during the period of exposure (units: volume/day)
$[X]_y$	-	Concentration of substance "X" in medium "y"

APPENDIX G

SAMPLE RISK ASSESSMENT SUMMARY FORMS

Summary Tables in Risk Assessment

The risk characterization submitted as part of the Phase II Report contains much information which can be summarized in tables. Summary tables, used effectively, can convey important information in a clear and concise manner. Such tables facilitate the review of the Phase II Report.

Summary tables can not and must not replace a detailed discussion and analysis of a disposal site. Tables are typically included in the text of the document to supplement, rather than replace the discussion.

The information presented in the summary tables should be clearly referenced so that a reader may easily identify the source of the information presented.

This appendix presents several samples of summary tables which could be included as part of the Phase II risk characterization report. The risk assessor, in preparing the report, will want to consider the type of information which is easily summarized and the format which will best present that information.

Again, as an aid in the review process, summary tables which appear within the report may be collected and presented as an appendix to that report. Alternatively, a list may be made of the title and location of each table within the report, and the list may be included as part of the Table of Contents.

Department of Environmental Quality Engineering

SAMPLE Risk Assessment Summary Form

Site Name: Anywhere Industrial Inc. **Site ID:** 00-000-0000

Location: Anywhere, MA **Region:** Southeast

DEQE Contact: Site Manager's Name **Telephone:** 000-000-0000

I. SITE HISTORY/DESCRIPTION

A. At what point in the MCP investigation/remediation process has this assessment been prepared?

This report is being prepared to fulfill the requirements of a Phase II Investigation, as described in the Massachusetts Contingency Plan (310 CMR 40.000)

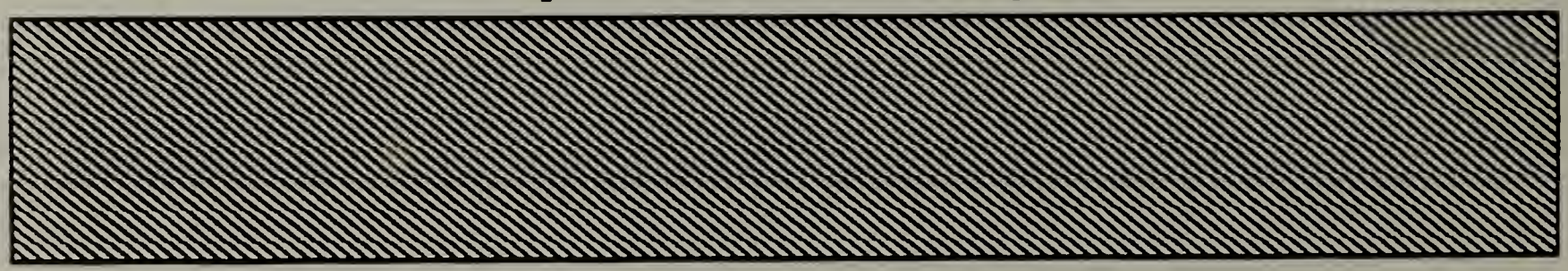
OR, perhaps: This Report has been prepared to evaluate a potential Imminent Hazard during a Phase I investigation.

B. Briefly describe the site and its history.

The description of the site may briefly trace the historical uses of the location, the current use of the site and the physical layout of the disposal site and surrounding area.

As noted below, maps may be provided or referenced (if they appear elsewhere in the document). These maps could describe the topography of the site, the area of contamination, the soil and/or grounwater characteristics, etc...

C. Please attach a detailed map of the site and surrounding area.



D. FORESEEABLE FUTURE USE

The MCP requires that the risks associated with OHM at or from a disposal site be assessed for all current and reasonably foreseeable future uses of the disposal site and the surrounding environment. These uses must be clearly stated in the risk assessment, and they may be summarized in a table for reference:

EXAMPLE:

Location (on-site, off-site)	Present Use	Foreseeable Future Use(s)	Documentation/ Justification
Vacant Lot (on-site)	neighborhood sports	Residential	zoning/ planned development
Groundwater (downgradient from site)	none	none	existing connection to town water/ letter from municipal water board and DEQE Division of Water Supply
small pond (off-site)	fishing	fishing/ swimming/ boating	town plans recreational facility

E. APPLICABLE OR SUITABLY ANALOGOUS STANDARDS, GUIDELINES OR POLICIES

The MCP requires that comparisons of exposure point concentrations be made to existing standards, predetermined clean-up levels, or standards, guidelines and policies. These values may be summarized and referenced.

EXAMPLE:

Chemical	Medium	S/G/P/PCUL	Reference
Silver	Drinking Water	50 ug/L	310 CMR 22.00 (standard)
Acetone	Air	68 ppb	DEQE AAL (guideline)

II. Hazard Identification

A. Oil and Hazardous Material Reported at the Site.

The sampling data collected as part of the Phase II investigation and used in the Risk Assessment should be summarized in one or more tables which would include the following information:

- Summary of chemicals reported at the site
- sampling medium and methodology
- number of "hits" and range of values detected and mean value
- site-specific "background" level for each chemical in each medium

EXAMPLE:

Medium Sampled: Groundwater Analytical Methodology: EPA 624/HSL List

Chemical	reported concentrations mean value	(range)	"background" level mean	(range)
Dichloromethane	17 mg/l	5 - 30	ND	-

B. Toxicity Profiles and Health Effects

For each Oil or Hazardous Material identified, a Toxicity Profile should be included as part of the Risk Assessment. A summary table may be prepared which would indicate the type of Toxicity Profile provided (in-depth, or a brief summary) and the major health effects associated with exposure to that chemical (both carcinogenic and non-carcinogenic effects).

EXAMPLE:

Chemical	Toxicity Profile in-depth	brief	Health Effects non-carcinogenic	carcinogenic
Dichloromethane		X	Liver Toxicity (oral)	liver tumors (oral) mammary & pulmonary carcinoma (inhal)

III. DOSE RESPONSE

The chemical specific toxicity values used to estimate both non-carcinogenic and carcinogenic risks should be summarized in one or more tables.

A. Non-carcinogenic Health Effects

The specific toxicity value(s) used to evaluate non-carcinogenic risks will depend upon the information available for the OHM and the scenario to be evaluated.

EXAMPLE:

Chemical	RfD (or other chronic allowable intake)	(O)ral / (I)nhal.	AIS (or other allowable subchronic dose)	Applicable time period	(O)ral / (I)nhal.
Dichloromethane	0.06 mg/kg-day[1]	O	1.3 mg-kg/day[2]	1 day	O

References:

1. US EPA Reference Dose (RfD) from IRIS file, 11/1/87
2. from 1-day Health Advisory (10 -g Child), US EPA 3/31/87

- references should be included for ALL toxicity values
- These values are developed for exposure by either oral or inhalation exposures. Please indicate whether each value is for an (o)ral or (i)nhalation exposure.

B. Carcinogenic Effects

The Slope (or Potency) Value derived by the EPA's Carcinogen Assessment Group (CAG) should be included for each OHM for which a value has been developed. The EPA's classification (Group A, B1, B2 or C) should also be included.

EXAMPLE:

Chemical	Slope Factor $(mg/kg/day)^{-1}$	Group	(O)ral/ (I)nhalation	reference
Dichloromethane	0.0075 0.014	B2 B2	Oral Inhalation	IRIS 11/1/87 IRIS 11/1/87

IV. EXPOSURE ASSESSMENT

An exposure pathway consists of four necessary elements:

(1) a source and mechanism of chemical release to the environment,

(2) an environmental transport medium (e.g., air, groundwater) which carries the OHM from the source of contamination,

(3) a point of potential human contact with the contaminated medium (referred to as the Exposure point), and

(4) a human exposure route (e.g., drinking water ingestion) at the contact point (the mechanism or pathway by which an individual may be exposed to the OHM)

Tables 1. & 2. (Taken from the Superfund Public Health Evaluation Manual) list common examples of these elements, leading from the source of contamination to a potential human exposure. A particular disposal site may include some unique elements which are not included on these lists, but which must be evaluated in the Risk Assessment.

A. A summary table may be prepared which details these four elements for each potential exposure pathway considered in the Risk Assessment. Note should be made of those pathways which were considered quantitatively, which were treated qualitatively, and which were dismissed from further consideration.

EXAMPLE:

Release Source	Release Mechanism	Transport/ Exposure Medium	Exposure Point	Exposure Route	REFERENCE
lagoon	volatilization	air	playground	inhalation	(1)
leaking drums	leakage	soil	on-site vacant lot	ingestion	(2)
leaking drums	leakage	soil	on-site vacant lot	dermal contact	(3)
soil	run-off	surface water	lake-side homes	ingestion of fish	(4)

1. Risks estimated and determined to be insignificant - see page 324.
2. Risks estimated - see page 326
3. Risks estimated - see page 328
4. Fish sampled and found to be free of contamination. See discussion, p. 330.

** Table 1 **

COMMON CHEMICAL RELEASE SOURCES

Release Medium	Release Mechanism	Release Source
AIR		
	Volatilization	Surface Wastes, lagoons, ponds, pits, spills Contaminated surface soil Contaminated wetlands Leaking drums
	Fugitive dust generation	Contaminated surface soil Waste piles
SURFACE WATER		
	Surface Runoff	Contaminated surface soil
	Episodic overland flows	Lagoon overflow Spills, leaking containers
	Groundwater seepage	Contaminated groundwater
GROUNDWATER		
	Site leaching	Surface or buried wastes Contaminated soil
SOIL		
	Site leaching	Surface or buried wastes
	Surface runoff	Contaminated surface soil
	Episodic overland flows	Lagoon overflow Spills
	Fugitive dust generation/ deposition	Contaminated surface soil Waste piles
	Tracking	Contaminated surface soil

from Superfund Public Health Evaluation Manual
EPA 540/1-86/060 October 1986 p.42

** Table 2 **

TYPICAL EXPOSURE POINTS FOR CHEMICAL

RELEASES FROM HAZARDOUS WASTE SITES

Transport/Exposure Medium	Typical Exposure Point	Major Exposure Routes
AIR		
	Nearest Residence to source	Inhalation
	Nearest population magnet (e.g., shopping center, school, industrial park)	Inhalation
	Other residence/population at point of highest concentration	Inhalation
SURFACE WATER		
	Withdrawal point for potable use	Ingestion, Dermal Inhalation
	Withdrawal point for agricultural use	Inhalation, Ingestion (food), Dermal
	Withdrawal point for other uses (e.g., industrial)	Inhalation, Dermal
	Nearest point for swimming/ contact sports	Ingestion, Dermal
	Nearest point for fishing	Ingestion (food)
GROUNDWATER		
	Nearest potable well (public or private)	Ingestion, Dermal Inhalation
	Nearest agricultural well	Inhalation, Ingestion (food), Dermal
	Nearest well for other uses (e.g., industrial)	Inhalation, Dermal
SOIL		
	On-site	Dermal, Ingestion
	Immediately adjacent to site (if site is restricted)	Dermal, Ingestion
	Nearest cropland	Ingestion (food)

from Superfund Public Health Evaluation Manual,
EPA 540/1-86/060 October 1986 p.46

B. EXPOSURE PROFILES

Exposure Profiles must be developed which describe each receptor of concern, the exposure point(s) contact with the oil or hazardous material is thought to occur, and the activity (-ies) through which such contact may occur. (See the discussion of Exposure Profiles in the text.) Such information may be summarized for each Exposure Profile evaluated.

EXAMPLE:	Receptor of Concern	Exposure Point	Activities of Potential Concern
	Child, ages 2-6	neighborhood playground	daily play in contaminated soil during the summer months (5 times/week)
	Adult	nearest residence	inhalation of air, ingestion of water, contact with soil during gardening

Note that Exposure Profiles should be developed for the current and foreseeable future uses of the disposal site and surrounding environment.

C. ESTIMATION OF AVERAGE DAILY DOSE

The estimation of risk (both carcinogenic and non-carcinogenic) may involve a large number of repetitive calculations to determine the Average Daily Dose of oil or hazardous materials to which the receptor(s) of concern are exposed. These calculations are best done on a computerized spreadsheet. It is extremely important, however, that the equations used to calculate the doses be explicitly stated, and that the assumptions used in the equations be stated and referenced. A review of the Phase II Risk Characterization is impossible if the reviewer can not duplicate these calculations.

EXAMPLE:

Scenario:

CHEMICAL	$[OHM]_{SO}$ (mg/kg)	BAF_{dermal}	SA (cm^2/day)	MS (mg/cm^2)	F (events/day)	D_1 (day/event)	D_2 (days)	BW_{avg} (kg)	AP (years)	C $\left(\frac{kg \cdot year}{mg \cdot day}\right)$	LADD (mg/kg/day)
TCE	378	0.5	1500	0.51	1	1	120	70	70	2.7E-06	0.67
Chloroform	45	0.5	750	0.51	1/7	1	1400	20	70	2.7E-06	3.3E-03

V. Characterization of Risk

For Method 3.b. sites, risk must be characterized through the comparison of exposure point concentrations to any existing public health standards and the comparison of Total Site Risks to the Total Site Risk Limits presented in the Contingency Plan. (See the text discussion, Section V.) The estimation of Total Site Risk involves the addition of the chemical- and exposure route- specific risks associated with each exposure experienced by the receptor(s) of concern. This process may be extremely complex.

	Chemical-Specific Risks (R)	Route-Specific Risks (R)	Total Site Risk For this Receptor of Concern
AIR	$R_{BENZENE} + R_{CARBON\ TETRACHLORIDE} + R_{DICHLOROMETHANE} =$	R_{AIR}	
		+	
DRINKING WATER	$R_{ARSENIC} + R_{BENZENE} + R_{DICHLOROMETHANE} + R_{TRICHLOROETHYLENE} =$	$R_{DRINKING\ WATER}$	$R_{Total\ Site}$
		+	
SOIL	$R_{ARSENIC} + R_{BaP} =$	R_{SOIL}	

Summary Tables may be developed which would include:

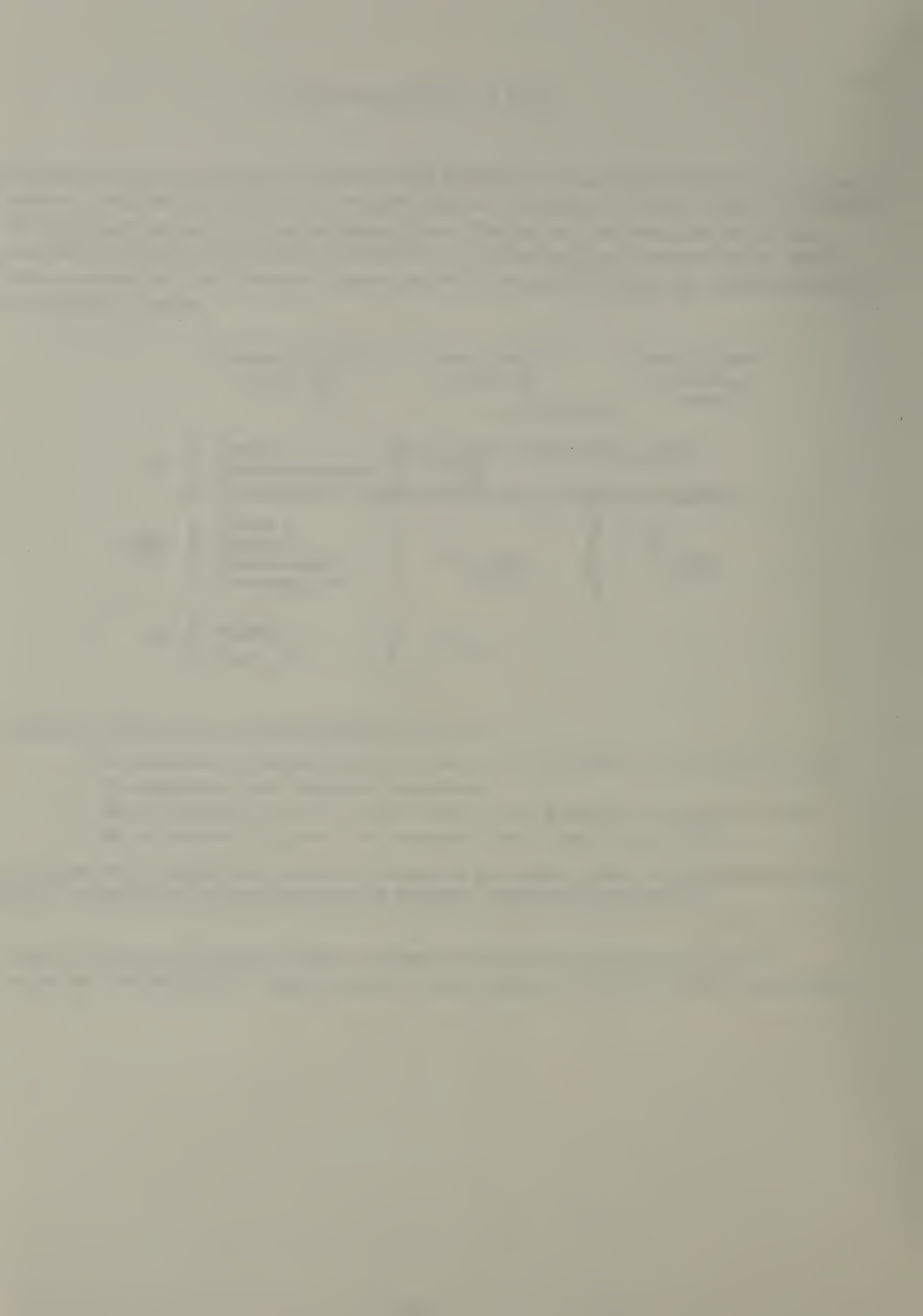
1. The estimation of Chemical-specific risks from the estimated Average Daily Doses and the appropriate Dose-Response information.
2. The summation of Chemical-specific risks to yield Exposure-route-specific risks.
3. The summation of Exposure-route-specific risks to yield Total Site Risk.

TOTAL SITE RISKS (BOTH EXCESS LIFETIME CANCER RISK AND HAZARD INDEX) WILL BE ESTIMATED FOR EACH RECEPTOR OF CONCERN FOR WHOM AN EXPOSURE PROFILE WAS DEVELOPED!!

FINALLY, A table may be included which summarizes the Receptors of Concern and their respective Total Site Risks. Comparisons may then be easily made with the Total Site Risk Limits.

APPENDIX H

SAMPLE WORKSHEETS USED IN THE CHEMICAL HEALTH EFFECTS METHODOLOGY



DATA SOURCES USED IN THE CHEMICAL HEALTH EFFECTS METHODOLOGY

ACUTE/CHRONIC TOXICITY

o	NIOSH	National Institute of Occupational Safety and Health
o	ACGIH	American Conference of Governmental Industrial Hygienists
o	OSHA	Occupational Safety and Health Administration
o	ATSDR	Agency for Toxic Substances and Disease Registry - Toxicological Profiles
o	EPA	Integrated Risk Information System (IRIS)
o	Other	Primary science literature, as needed (e.g., no occupational data)

CARCINOGENICITY

o	IARC	International Agency for Research on Cancer
o	NTP	National Toxicology Program
o	CAG	Carcinogen Assessment Group (EPA)
o	ATSDR	Toxicological Profiles
o	Other	Other government agencies, Gold et. al., primary science literature, as needed (e.g., new data)

MUTAGENICITY

o	IARC	International Agency for Research on Cancer
o	GENE-TOX	Genetic Toxicology Program
o	ATSDR	Toxicological Profiles
o	Other	Primary science literature, as needed

REPRODUCTIVE/DEVELOPMENTAL

o	EPA	Integrated Risk Information System (IRIS)
o	Other	Primary science literature, as needed

SELECTION OF MAOL WORKSHEET

FOR:
CAS CODE:
DATE:
MAOL CHOSEN:

OCCUPATIONAL LIMITS	HEALTH EFFECTS/BASIS FOR LIMITS	EFFECTS AT OR BELOW OCCUPATIONAL LIMIT	ADDITIONAL DATA	EFFECTS NOT ACCOUNTED FOR	BASIS FOR THE DEPARTMENT'S DECISION	REFERENCES
NIOSH:						
ACGIH:						
OSHA:						

ACUTE /CHRONIC TOXICITY WORKSHEET

FOR:
CAS CODE:
DATE:

SEVERITY FACTOR:
MAOL:
SCORE:

	OCCUPATIONAL LIMITS	
	NIOSH	ACGIH
PRINCIPAL ACTION		
TOXICITY		

	HEALTH EFFECTS		
	SHORT TERM EXPOSURE	LONG TERM EFFECTS	COMBINED SHORT AND LONG TERM EXPOSURES
SKIN			
EYES			
RESPIRATORY TRACT			
LIVER & KIDNEY			
NERVOUS SYSTEM			
OTHER			
CARCINOGEN MUTAGEN			
DEVELOPMENTAL REPRODUCTIVE			

	DATA		
LOWEST EFFECT LEVEL REPORTED			
ANIMAL OR HUMAN			
COMMENTS			
REFERENCES			

CARCINOGENICITY WORKSHEET **#1** **BIOASSAY RESULTS**

[Sites that were significant]

Species	Sex	Site	Tumor	Statistics	NTP Results	incidence C	L	M	H	nstag q°	q1	qa	q3	q*1

CARCINOGENICITY WORKSHEET #2

DOSE ADJUSTMENT

SURFACE AREA ADJUSTED DOSE ( )	LIFETIME AVERAGE DOSE ( )	WEIGHT ( )	TREATMENT CHARACTERISTICS ( )	ADMINISTERED DOSE ( )

CARCINOGENICITY WORKSHEET #3

POTENCY VALUE SELECTION

CHEMICAL: _____ CAS: _____

POTENCY VALUE:

Source: reference _____
species _____
sex _____
route _____
survival effects _____
weight effects _____
incidence adjusted _____

MTD comment:

q_c _____ q_1 _____ q_1^* _____ LLE _____ final q_1^* _____

Site/Tumor: _____ Dose Response: _____

Background Incidence: _____

Non Neoplastic Pathol: _____

RATIONAL FOR SITE SELECTION:

RATIONAL FOR STUDY SELECTION:

CARCINOGENICITY WORKSHEET #4

QUALITATIVE EVIDENCE SUMMARY

IARC HUMAN _____ ANIMAL _____

COMMENT:

SOURCE:

NTP HUMAN _____ ANIMAL _____

COMMENT:

SOURCE:

CURRENT ACTIVITY:

EPA GROUP _____ HUMAN _____ ANIMAL _____

COMMENT:

SOURCE:

OTHER:

CARCINOGENICITY WORKSHEET #5

NON-THRESHOLD EFFECTS SUMMARY

CHEMICAL:_____ CAS:_____ M.W.:_____

CHEM weight of evidence - Carcinogen:_____ Score: C _____
SAR: _____ Mutagen:_____ M _____
Other weight of evidence: _____

UNIT RISK VALUE

CAG Unit risk:
Source:

DEQE Unit risk:
Source:
pk/met data used?

Other:

Rational for selection of unit risk value:

MUTAGENICITY WORKSHEET

FOR:
DATE:

INITIAL:
CAS CODE:
SCORE:

CODES	SYSTEM	ENDPOINT	RESULTS	COMMENTS
			INTERMEDIATES / FINAL	
GROUP I: MAMMALIAN, IN VIVO				
SLT	B	G		
MST	B	M		
'DSM'	B	C		
DCA'	B	C		
DLT	B	G		
HTT	B	G		
MNT	B	G		
GROUP II : PRIMARY SHORT - TERM TESTS				
V79		G		
CHO	D	M		
L51	D	M		
SAL	E	M		
WP2/WPU	E	M		
SRL	F	M		
HMA	B/E	M		
CY5/CY8	A	C		
CY#/CY%	B	C		
CYO/CY9	B	C		
CY7/CYZ	C	C		
CY&	D	C		
MN7	C	C		
MN&	D	C		
DHT	E	C		
SCY	A	C		
SCI/SCW/SCL	C	C		
SC3/SC2	B/D	C		
ASG	G	C		
YEH/YEC	G	C		
RE2/REI	E	N		
REW/REX	E	N		
SPH	A	X		
CTB/CTH	D	X		
CTM	D	X		
CTC/CTF	D	X		
CTR/CTK/CT7	D	X		
CTA	D	X		
GROUP III: SECONDARY SHORT TERM TESTS				
YEF/YER/YEY/YEZ	G	M		
ASF/ASR	G	M		
NEF/NER	G	M		
PGM	H	M		
BFU	A	M		
DAC/DAP/DAG	F	C		
YEN/ASN/NEN	G	C		
MNP	H	C		
PYC	H	C		
SPI/SPR/SPA	B	X		
SPF	B	X		
UDH	C	N		
UDT	C	N		
UDP	D	N		

LEGEND

ENDPOINT

M= Gene or Point Mutation
N= DNA -related effects
C= Chromosomal Effects
G= Gen. group includes several endpoints
X= Ancillary Tests

SYSTEM

A= Human, in vivo
B= Other mammal in vivo
C= Human, in vitro
D= Other Mammal , in vitro
E= Bacteria
F= Drosophila
G= Fungi
H= Plants

DEVELOPMENTAL/REPRODUCTIVE TOXICITY WORKSHEET

Assessment of Studies for Scoring

For:
CAS Code:
Final Score:
Final Weight of Evidence:
Date:

STUDY #	AUTHOR	ANIMAL ROUTE	DOSE RESPONSE	EFFECT AND LOWEST DOSE	MATERNAL TOXICITY	LOEL	RISK RATIO	QUALITY OF STUDY	WEIGHT OF EVIDENCE	SCORE

DEVELOPMENTAL/REPRODUCTIVE TOXICITY WORKSHEET

DESCRIPTION OF EFFECTS

study #_____
page #____

FOR:
CAS CODE:
DATE:

REFERENCE:
QUALITY:
STUDY DOSE:

EFFECT:
LOEL:
RISK RATIO:

ANIMAL / ROUTE	EXPOSURE CONDITIONS	DOSE	TERATOGENICITY	EMBRYO / FETAL TOXICITY	MATERNAL/ PATERNAL REPROD. TOXICITY	PERI/POST -NATAL TOXICITY	COMMENTS

DEVELOPMENTAL/REPRODUCTIVE TOXICITY WORKSHEET

GENERAL INFORMATION

FOR: study #

CAS:

REFERENCE:

EXPERIMENTAL DESIGN

o Controls

_____ concurrent

_____ historical

o Dosing Regimen

_____ two or more doses. Number of doses = _____

_____ high dose non-toxic to dams

_____ low dose (= a No Observed Effect Level)

o Number of Animals Treated (does not pertain to fertility and reproductive study protocol)

_____ at least 20 rodents

_____ less than 20 rodents (Number = _____)

_____ at least 10 rabbits

_____ less than 10 rabbits (Number = _____)

_____ primates (Number = _____)

DATA REPORTED AS:

___ Number of Affected Fetuses

_____ per litter

_____ per treatment group

_____ per total exposed

___ Percent of Affected Fetuses

_____ per litter

_____ per treatment group

_____ per total exposed

_____ Average Values Per Pup

_____ Number of Affected Litters

_____ per treatment group

_____ per total exposed

_____ Percent of Affected Litters

_____ per treatment group

_____ per total exposed

STATISTIC: _____ Yes _____ No

TYPE OF STUDY:

_____ Teratogenic Study

_____ Fertility and Reproductive Study

_____ Perinatal or Postnatal Study

DEVELOPMENTAL/REPRODUCTIVE TOXICITY WORKSHEET

Teratogenic Study

FOR: CAS: REFERENCE:

STUDY DESIGN

_____ Control Group _____ Untreated Males
_____ Treatment period covers time of organ formation
_____ Fetus delivered by Cesarian section one or two days prior to partuition.

PARAMETERS EVALUATED

o FDA recommended

_____ number of fetuses _____ placement in uterine horn
_____ correlation of fetuses with corpus lutea
_____ number of live and dead fetuses
_____ number of early resorptions
_____ early _____ late
_____ fetal weight _____ external anomalies
_____ internal anomalies
_____ 1/3 for dissection or Wilson slicing method for visceral anomalies; if not 1/3, then:_____
_____ 2/3 for clearing and bone-staining with alizarin: if not 2/3, then: _____

o Other Parameters Evaluated

_____ biochemistry _____ fetal histology
_____ cellular morphology _____ hematology
_____ maternal toxicity
_____ body weight _____ organ weight
_____ death _____ percent pregnant
_____ food consumption _____ water consumption
_____ clinical signs of toxicity
_____ others: _____
_____ crown-rump length _____ placenta weight
_____ organ weight _____ other:_____

CONCLUSIONS ON QUALITY OF STUDY:

DEVELOPMENT/REPRODUCTIVE TOXICITY WORKSHEET

FERTILITY AND REPRODUCTIVE STUDY

FOR:
CAS CODE:
REFERENCE:

STUDY DESIGN

- Number of Animals (minimum)

___ 10 Males (rodents)
___ 20 Females (rodents)
___ 10 Females (rabbits)
___ Number of Primates:
___ 10 Males/20 Females (mating studies)
___ other:_____

- Dosing Schedule

___ Minimum age of 40 days for males for premating exposure.
___ Female premating exposure following establishment of estrus cycle by daily vaginal smears.
___ Mating study
_____ premating exposure
_____ organogenesis exposure
_____ gestation exposure
_____ lactation exposure
___ Other:_____

PARAMETERS EVALUATED

- Non-mating studies

_____ Studies using males
_____ testes
_____ weight
_____ morphology
_____ histology
_____ biochemistry
_____ other_____
_____ sperm
_____ motility
_____ morphology
_____ Studies using females
_____ hormonal changes
_____ estrous changes
_____ changes in ovarian function
_____ other:_____

- Mating Studies

_____ preimplantation studies
_____ sacrafice on day 13 of gestation
_____ number and distribution of embryos
_____ presence of empty implantation sites
_____ number of embryos undergoing resorption
_____ uterine abnormalities
_____ other_____
_____ sacrafice on day 20 of gestation
_____ number of fetuses
_____ placement in uterine horn
_____ correlation of fetuses with corpus lutea
_____ number of live and dead fetuses
_____ number of resorptions
_____ early
_____ late
_____ fetal weight
_____ external anomalies
_____ internal anomalies
_____ one third for dissection or Wilson method for visceral anomalies.
_____ two thirds for clearing and bone staining with alizarin.
_____ biochemistry
_____ fetal histology
_____ cellular morphology
_____ maternal toxicity
_____ body weight
_____ organ weight
_____ death
_____ percent pregnant
_____ food consumption
_____ water consumption
_____ clinical signs of toxicity
_____ other_____
_____ crown-rump length
_____ hematology
_____ placenta weight

FOR:
CAS CODE:
REFERENCE:

_____Dams delivering
_____observe labor and delivery
_____calculate duration of gestation
_____observations
_____litter size
_____ratio of male to female pups
_____number of still born
_____number of live born
_____gross anomalies
_____skeletal observation
_____pup weight
_____day 1
_____day 4
_____day 21
_____other day: _____
_____behavior
_____biochemistry
_____Reproductive performance of offspring
_____number of generations = _____
_____age at production of first litter
_____ratio of males to females
_____runts
_____deaths
_____stillborn offspring
_____failure to breed
_____congenital abnormalities

CONCLUSIONS ON QUALITY OF STUDY:

DEVELOPMENT/REPRODUCTIVE TOXICITY WORKSHEET

PERINATAL AND POSTNATAL STUDY

FOR:
CAS CODE:
REFERENCE:

STUDY DESIGN

- Dosing Schedule

_____premating
_____organogenesis
_____gestation
_____perinatal
_____dams treated pups exposed through lactation
_____pups treated
_____other_____

PARAMETERS EVALUATED

_____observe labor and delivery
_____calculate duration of gestation
_____observations
_____litter size
_____ratio of males to females
_____number of stillborn
_____number of live born
_____gross anomalies
_____skeletal observation
_____biochemistry
_____continued dosing through lactation observe effects on
_____lactation
_____nursing
_____instinct
_____toxic effects
_____other_____

CONCLUSIONS ON QUALITY OF STUDY:

BIOASSAY SUMMARY SHEET

Chemical _____

Route _____

Source _____ CAS #_____

		Dose admin.			Dose adjust			Body Weight (g) 60 wk.			Body Weight (g) Terminal				Sig. dif.	Survival				Sig. dif.
		L	M	H	L	M	H	L	M	H	C	L	M	H		C	L	M	H	
Rat	M																			
	F																			
Mouse	M																			
	F																			
	M																			
	F																			

exposure information age at 1st dose_____
age at last dose_____
age at sac. _____
Total time dose_____

Sites not considered significant (sign. by statistics):

non neoplastic pathology at site:

ASSESSMENT OF STUDIES FOR SCORING

CHEMICAL:_____

Article No., Author Effect	Animal Route	Dose Response	Teratogenicity Effect lowest Dose	M. Embryofetal Toxicity Effect Lowest Dose	Maternal Toxicity	Reproductive Toxicity Maternal Effect/ Low dose	Reproductive Toxicity Paternal Effect Low dose	Post Developmental Effect Lowest Dose	LOEL mg/kg day	Risk Ratio	Quality of study

WEIGHT- OF -EVIDENCE | LOEL | RISK RATIO | SCORE

Appendix I

Specific Sets of Clean-up Levels Contained in 310 CMR 40.800

Clean-up Levels

At this time no sets of clean-up levels have been promulgated for 310 CMR 40.800. As sets of clean-up levels are developed, they will be proposed by the Department and undergo a public review process which will be the formal Massachusetts regulatory review process.

The Department will be working in conjunction with the Superfund Advisory Committee on this process.

Appendix J

Allowable Threshold Concentrations

(Adapted from CHEM)

Allowable Threshold Concentration

(ATC)

The acceptable daily dose used in the evaluation of inhalation exposures in Method 3.b. is not the oral Reference Dose, but a daily dose derived from the Allowable Threshold Concentrations (ATC), if available. The ATC value are adjusted Threshold Effects Exposure Limits (TELs, presented in CHEM).

SEE Section V.D. - Risk Characterization per 310 CMR 40.545(3)(g) 3.b.

This acceptable daily dose may be derived:

$$AD_{i\ inh} = ATC * 10\ m^3/day * 1/20\ kg * C$$

Where:

$AD_{i\ inh}$	=	The acceptable daily dose for exposure to substance i via inhalation.
ATC	=	The Allowable Threshold Concentration
$10\ m^3/day$	=	Average Child Ventilation Rate
1/20 kg	=	Inverse of the average Child Body Weight
C	=	Units Conversion Factor

The following Table contains Allowable Threshold Concentrations (adjusted TEL values abstracted from CHEM).

Allowable Threshold Concentrations (ATC)

CHEMICAL	CAS NUMBER	ATC ug/m3	ATC ppb
ACETALDEHYDE	75070	24	14
ACETONE	67641	800	340
ACRYLONITRILE	107131	6	3
ALKANES/ALKENES (not to exceed 25% hexane)		480	-
AMMONIA	7664417	24	34
ANILINE	62533	10	3
ASBESTOS	1332214	0.001 f/cm3	
BENZENE	71432	9	3
BENZYL CHLORIDE	100447	70	14
BERYLLIUM	7440417	0.01	-
1,3-BUTADIENE	106990	6	3
n-BUTYL ALCOHOL	71363	2060	680
CADMIUM	7440439	0.02	-
CALCIUM CHROMATE	13765190	0.02	-
CARBON DISULFIDE	75150	1	4
CARBON TETRACHLORIDE	56235	430	68
CHLORDANE	57749	0.7	0.04
CHLORINE	7782505	20	7
CHLOROBENZENE	108907	470	100
CHLOROETHANE	75003	3600	1400
CHLOROFORM	67663	660	140
CHLOROPRENE	126998	5	1
CHROMIC ACID	13765190	0.02	-
CHROMIUM (METAL)	7440473	7	-
CHROMIUM (VI) COMPOUNDS		0.02	-
COPPER	7440508	3	-
p-CRESOL	106445	120	27
CYCLOHEXANE	110827	1400	400
o-DICHLOROBENZENE	95501	400	68
p-DICHLOROBENZENE	106467	610	100
1,2-DICHLOROETHANE	107062	55	13
1,2-DICHLOROETHYLENE	540590	1100	270
DICHLOROMETHANE	75092	47	13
1,2-DICHLOROPROPANE	78875	470	100
DIETHYLAMINE	109897	40	13
DI(2-ETHYLHEXYL)-PHTHALATE	117817	7	0.5
DIMETHYLFORMAMIDE	68122	40	13
1,4-DIOXANE	123911	120	34
DIPHENYL	92524	2	0.3
DIPHENYLAMINE	122394	13	2
EPICHLOROHYDRIN	106898	3	1
ETHANOL	64175	250	140
ETHYL ACETATE	141786	2000	540

ATC VALUES, continued...

CHEMICAL	CAS NUMBER	ALLOWABLE THRESHOLD CONCENTRATIONS (ATC) ug/m3	ppb
ETHYL ACRYLATE	140885	3	1
ETHYLBENZENE	100414	590	140
ETHYLENE GLYCOL	107211	170	68
ETHYL ETHER	60297	1600	540
FLUORIDE	16984488	34	44
FORMALDEHYDE	50000	2	1
FURAN	110009	2	1
HEPTACHLOR	76448	1	0.05
HEXACHLOROCYCLO-PENTADIENE	77474	0.03	0.003
HEXACHLOROETHANE	67721	3	0.3
HEXACHLOROPHENE	70304	-	-
2-HEXANONE	591786	54	13
HYDRAZINE	302012	0.04	0.03
HYDROGEN CHLORIDE	7647010	10	7
HYDROGEN FLUORIDE	7664393	3	4
HYDROGEN SULFIDE	7783064	19	14
ISOAMYL ACETATE	123922	720	140
ISOBUTYL ACETATE	110190	970	200
ISOBUTYL ALCOHOL	78831	200	68
ISOPROPYL ACETATE	108214	1400	340
LEAD	7439921	1	-
LEAD SUBACETATE	1335326	1	-
LINDANE	58899	1	0.6
MALEIC ANHYDRIDE	108316	1	0.4
METHANOL	67561	36	27
2-METHOXY ETHANOL	109864	21	7
METHYL ACRYLATE	96333	48	14
METHYL BROMIDE	74839	26	7
METHYL ETHYL KETONE (MEK)	78933	160	54
METHYL ISOBUTYL KETONE (MIBK)	108101	280	68
METHYL MERCURY	7439976	0.02	-
METHYL METHACRYLATE	80626	110	27
MIREX	2385855	-	-
NAPTHALENE (including 2-methylnaphthalene)	91203	71	14
NICKEL (METAL)	7440020	1	-
NICKEL OXIDE	1313991	1	-
NITROBENZENE	98953	68	14
PENTACHLOROPHENOL	87865	0.07	0.01
PHENOL	108952	260	68
PHOSPHORIC ACID	7664382	1	0.3
PHTHALIC ANHYDRIDE	85449	8	1

ATC VALUES, continued...

CHEMICAL	CAS NUMBER	ALLOWABLE THRESHOLD CONCENTRATIONS (ATC) ug/m3	ppb
PCBs	1336363	0.02	-
PROPYL ALCOHOL	71238	670	270
PROPYLENE OXIDE	75569	65	27
RESORCINOL	108463	61	14
SELENIUM	7782492	3	-
SELENIUM SULFIDE	7446346	3	-
STYRENE	100425	580	140
SULFURIC ACID	7664939	14	3
1,1,2,2-TETRACHLORO-1,2-DIFLUOROETHANE	76120	5700	680
1,1,2,2-TETRACHLORO-ETHANE	79345	93	14
TETRACHLOROETHYLENE	127184	4600	680
TETRAHYDROFURAN	109999	800	270
TOLUENE	108883	51	14
TOLUENE DIISOCYANATE	584849	0.5	0.07
o-TOLUIDINE	95534	12	3
1,1,1-TRICHLORO-ETHANE	71556	5200	950
1,1,2-TRICHLORO-ETHANE	79005	74	14
TRICHLOROETHYLENE	79016	180	34
2,4,6-TRICHLORO-PHENOL	95954	-	-
TRIETHYLAMINE	121448	6	1
VANADIUM	1314621	1	-
VANADIUM PENTOXIDE	1314621	0.7	0.1
VINYL ACETATE	108054	190	54
VINYL CHLORIDE	75014	17	7
VINYLIDENE CHLORIDE	75354	5	1
XYLENES (m-,o-,p-,ISOMERS)	1330207	60	14

APPENDIX K

CHECKLIST FOR RISK CHARACTERIZATION REVIEW

Checklist for Risk Characterization Review

The following list summarizes the major issues which should be addressed in the Phase II Risk Characterization. This list will form the basis of the DEQE review of the risk characterization.

I. LAND USE

A. Are current and reasonably foreseeable uses of the disposal site clearly identified?
B. Are these uses incorporated into the baseline risk assessment?
C. Are the identified current and reasonably foreseeable uses of the disposal site and surrounding area consistent with the DEQE Regional Office's position?

II. HAZARD IDENTIFICATION & DOSE RESPONSE

A. Are all detected OHM carried through the risk assessment process?
B. Are adequate Toxicity Profiles presented? Are all important health endpoints identified and are toxicity values accurate and recent? Toxicity values are RfDs, potency values, etc.
C. Are all applicable or suitably analogous public health and environmental standards, guidelines and policies identified?

III. EXPOSURE ASSESSMENT

A. Are all migration pathways identified and incorporated into the assessment?
B. Are all appropriate receptors identified and incorporated (both current and reasonably foreseeable)? Are sensitive subgroups identified?
C. Are Exposure Point Concentrations properly identified or estimated for all OHM at all exposure points?
D. Are assumptions concerning frequency, duration, route and magnitude of exposures appropriate and defensible (when required by MCP)?
E. Are all doses calculated appropriately?

IV. RISK CHARACTERIZATION

A. Was the proper risk characterization method (1, 2, 3.a. or 3.b.) used for the disposal site?
B. Was the method executed properly?
C. If method 3.b. was used;
Was Total Site Cancer Risk Calculated?
Was the Hazard Index (or Indices) calculated?
D. Are the risk calculations and risk summaries presented in a way that makes it possible to evaluate the need for remediation?
E. Are the stated risks worst-case, most probable, or some other type?
F. Do the conclusions of the risk characterization clearly state:

i. Whether or not the potential for threshold-type health effects for the theoretical baseline exposure scenarios are of concern (Hazard Index greater than 0.2).
ii. Whether or not "total site cancer risks" exceed the total site cancer risk limit of 1×10^{-5}.

G. Does the Phase II Report state whether remediation is required per the criteria set forth in the MCP?

V. BACKGROUND

A. Have background concentrations been identified for the disposal site?